

**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 September 30, 2019

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

(State or other jurisdiction of incorporation or organization)

36-3898269

(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)

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock, par value \$0.001	TGTX	Nasdaq Capital Market

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 99,561,434 shares of the registrant's common stock, \$0.001 par value, outstanding as of November 5, 2019.



TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2019

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the captions “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, 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. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about our:

- 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;
- products being accepted 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;
- availability of 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 and its 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.

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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this report and the documents that we have filed as exhibits to this report completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Any forward-looking statements contained in this report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. 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 obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This report also contains estimates, projections and other information concerning our industry, our business and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL INFORMATION

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

	September 30, 2019 (Unaudited)	December 31, 2018 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,675	\$ 41,958
Short-term investment securities	27,776	26,943
Prepaid research and development	7,040	9,691
Other current assets	864	439
Total current assets	80,355	79,031
Restricted cash	1,248	1,241
Leasehold interest, net	2,157	2,294
Equipment, net	275	251
Right of use asset	8,493	—
Goodwill	799	799
Total assets	\$ 93,327	\$ 83,616
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 31,780	\$ 36,377
Other current liabilities	44,035	219
Lease liability – current portion	1,365	—
Accrued compensation	3,017	2,258
Total current liabilities	80,197	38,854
Deferred rent	—	1,462
Deferred revenue, net of current portion	800	914
Long-term debt	28,741	—
Lease liability – non current	9,380	—
Long-term liabilities	—	18,350
Total liabilities	119,118	59,580
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of September 30, 2019 and December 31, 2018)	—	—
Common stock, \$0.001 par value per share (150,000,000 shares authorized, 96,670,197 and 83,911,855 shares issued, 96,628,888 and 83,870,546 shares outstanding at September 30, 2019 and December 31, 2018, respectively)	97	84
Additional paid-in capital	635,989	552,531
Treasury stock, at cost, 41,309 shares at September 30, 2019 and December 31, 2018	(234)	(234)
Accumulated deficit	(661,643)	(528,345)
Total stockholders' (deficit) equity	(25,791)	24,036
Total liabilities and stockholders' (deficit) equity	\$ 93,327	\$ 83,616

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)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
License revenue	\$ 38	\$ 38	\$ 114	\$ 114
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	—	—	100	4,000
Noncash compensation	1,482	644	4,323	4,391
Other research and development	56,503	32,754	118,814	98,724
Total research and development	<u>57,985</u>	<u>33,398</u>	<u>123,237</u>	<u>107,115</u>
General and administrative:				
Noncash compensation	593	(817)	1,391	7,037
Other general and administrative	2,321	1,785	6,580	6,212
Total general and administrative	<u>2,914</u>	<u>968</u>	<u>7,971</u>	<u>13,249</u>
Total costs and expenses	<u>60,899</u>	<u>34,366</u>	<u>131,208</u>	<u>120,364</u>
Operating loss	<u>(60,861)</u>	<u>(34,328)</u>	<u>(131,094)</u>	<u>(120,250)</u>
Other expense (income):				
Interest expense	1,537	221	3,388	657
Other income	(468)	(598)	(1,183)	(1,285)
Total other expense (income), net	<u>1,069</u>	<u>(377)</u>	<u>2,205</u>	<u>(628)</u>
Net loss	<u>\$ (61,930)</u>	<u>\$ (33,951)</u>	<u>\$ (133,299)</u>	<u>\$ (119,622)</u>
Basic and diluted net loss per common share	<u>\$ (0.69)</u>	<u>\$ (0.43)</u>	<u>\$ (1.55)</u>	<u>\$ (1.61)</u>
Weighted average shares used in computing basic and diluted net loss per common share	<u>89,667,979</u>	<u>78,221,069</u>	<u>85,911,878</u>	<u>74,399,243</u>

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

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

	Common Stock			Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount			Shares	Amount		
Balance at January 1, 2018	73,181,750	\$ 73	\$ 422,017	41,309	\$ (234)	\$ (354,863)	\$ 66,993	
Issuance of restricted stock	87,500	*	*	—	—	—	—	
Forfeiture of restricted stock	(123,911)	*	*	—	—	—	—	
Issuance of common stock in At-the-Market offerings (net of offering costs of \$0.9 million)	3,989,344	4	52,426	—	—	—	52,430	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	7,337	—	—	—	7,337	
Net loss	—	—	—	—	—	(41,529)	(41,529)	
Balance at March 31, 2018	77,134,683	\$ 77	\$ 481,781	41,309	\$ (234)	\$ (396,392)	\$ 85,232	
Issuance of restricted stock	1,333,011	1	(1)	—	—	—	—	
Forfeiture of restricted stock	(6,750)	*	*	—	—	—	—	
Issuance of common stock in At-the-Market offerings (net of offering costs of \$1.0 million)	3,744,605	4	52,018	—	—	—	52,022	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	4,264	—	—	—	4,264	
Shares issued in connection with in-licensing agreements	333,868	*	4,000	—	—	—	4,000	
Net loss	—	—	—	—	—	(44,142)	(44,142)	
Balance at June 30, 2018	82,539,417	\$ 82	\$ 542,062	41,309	\$ (234)	\$ (440,534)	\$ 101,376	
Issuance of restricted stock	100,700	*	*	—	—	—	—	
Forfeiture of restricted stock	(24,785)	—	—	—	—	—	—	
Issuance of common stock in At-the-Market offerings (net of offering costs of \$0.1 million)	358,000	—	4,492	—	—	—	4,492	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	(173)	—	—	—	(173)	
Net loss	—	—	—	—	—	(33,951)	(33,951)	
Balance at September 30, 2018	82,973,332	\$ 83	\$ 546,380	41,309	\$ (234)	\$ (474,485)	\$ 71,744	

	Common Stock			Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount			Shares	Amount		
Balance at January 1, 2019	83,911,855	\$ 84	\$ 552,531	41,309	\$ (234)	\$ (528,345)	\$ 24,036	
Issuance of restricted stock	23,000	*	*	—	—	—	—	
Warrants issued with debt financing	—	—	993	—	—	—	993	
Forfeiture of restricted stock	(67,628)	*	*	—	—	—	—	
Issuance of common stock in public offering (net of offering costs of \$0.2 million)	4,715,000	5	27,494	—	—	—	27,499	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	1,882	—	—	—	1,882	
Net loss	—	—	—	—	—	(35,156)	(35,156)	
Balance at March 31, 2019	88,582,227	89	582,900	41,309	(234)	(563,501)	19,254	
Issuance of restricted stock	1,245,080	1	(1)	—	—	—	—	
Forfeiture of restricted stock	(38,418)	*	*	—	—	—	—	
Issuance of common stock in public offering	—	—	11	—	—	—	11	
Issuance of common stock in At-the-Market offerings (net of offering costs of \$0.5 million)	3,616,359	3	28,392	—	—	—	28,395	
Compensation in respect of restricted stock granted to	—	—	1,757	—	—	—	1,757	

employees, directors and consultants													
Net loss	—		—		—		—	(36,212)	(36,212)				
Balance at June 30, 2019	93,405,248	\$	93	\$	613,059		41,309	\$	(234)	\$	(599,713)	\$	13,205
Issuance of restricted stock	318,440		*		*		—		—		—		—
Forfeiture of restricted stock	(5,334)		—		—		—		—		—		—
Issuance of common stock in At-the-Market offerings (net of offering costs of \$0.4 million)	2,943,460		4		20,755		—		—		—		20,759
Compensation in respect of restricted stock granted to employees, directors and consultants	—		—		2,075		—		—		—		2,075
Shares issued in connection with in-licensing agreements	8,383		—		100		—		—		—		100
Net loss	—		—		—		—		—		(61,930)		(61,930)
Balance at September 30, 2019	<u>96,670,197</u>	<u>\$</u>	<u>97</u>	<u>\$</u>	<u>635,989</u>		<u>41,309</u>	<u>\$</u>	<u>(234)</u>	<u>\$</u>	<u>(661,643)</u>	<u>\$</u>	<u>(25,791)</u>

* 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)

	Nine months ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (133,299)	\$ (119,622)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	5,714	11,428
Noncash licensing expense	100	4,000
Depreciation	72	64
Amortization of premium on investment securities	(209)	(51)
Amortization of debt issuance costs	539	—
Amortization of leasehold interest	137	98
Noncash change in lease liability and right-of-use asset	1,921	—
Change in fair value of notes payable and accrued interest	28	(37)
Changes in assets and liabilities:		
Decrease (increase) in prepaid research and development and other current assets	2,226	(3,421)
Decrease in accrued interest receivable	—	28
(Decrease) increase in accounts payable and accrued expenses	(3,837)	12,321
Decrease in lease liability	(1,129)	—
Increase in interest payable	787	—
Increase in other current liabilities	24,651	—
Increase in deferred rent	—	71
Decrease in deferred revenue	(114)	(114)
Net cash used in operating activities	<u>(102,413)</u>	<u>(95,235)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(97)	(84)
Investment in short-term securities	(23,125)	(24,574)
Proceeds from maturity of short-term securities	22,500	25,600
Net cash (used in) provided by investing activities	<u>(722)</u>	<u>942</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	76,664	108,945
Proceeds from debt financings	29,675	—
Financing costs paid	(480)	—
Net cash provided by financing activities	<u>105,859</u>	<u>108,945</u>
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2,724	14,652
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	<u>43,199</u>	<u>57,305</u>
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	<u>\$ 45,923</u>	<u>\$ 71,957</u>
Reconciliation to amounts on consolidated balance sheets:		
Cash and cash equivalents	\$ 44,675	\$ 70,718
Restricted cash	1,248	1,239
Total cash, cash equivalents and restricted cash	<u>\$ 45,923</u>	<u>\$ 71,957</u>
NONCASH TRANSACTIONS:		
Deferred financing costs	\$ 988	\$ —
Warrants issued with debt financing	\$ 993	\$ —
Shares issued in connection with in-licensing	\$ 100	\$ —

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

TG Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (unaudited)

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 dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL and NHL, with ublituximab also in pivotal trials for MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily inhibitor of PI3K delta. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K delta inhibitors. When used together in combination therapy, ublituximab and umbralisib are referred to as “U2”. Additionally, we have recently brought into Phase 1 clinical development TG-1501, an anti-PD-L1 monoclonal antibody, TG-1701, a covalently-bound Bruton’s Tyrosine Kinase (BTK) inhibitor, and TG-1801, an anti-CD47/CD19 bispecific antibody.

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, 2018. The accompanying condensed December 31, 2018 balance sheet has been derived from these statements. The results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

In December 2018, the Company created an Australian corporation, TG Therapeutics AUS Pty Ltd, as a wholly-owned subsidiary. This corporation’s functional currency, the Australian dollar, is also its reporting currency, and its financial statements are translated to U.S. dollars, the Company’s reporting currency, prior to consolidation. The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, and all intercompany accounts and transactions have been eliminated in consolidation.

Liquidity and Capital Resources

We have incurred operating losses since our inception, expect to continue to incur operating losses for the foreseeable future, and may never become profitable. As of September 30, 2019, we have an accumulated deficit of approximately \$661.6 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities, as well as debt financings. 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 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 September 30, 2019, we had \$72.5 million in cash and cash equivalents, and investment securities. The Company believes its cash, cash equivalents, and investment securities on hand as of September 30, 2019 along with the additional capital raised in the fourth quarter of 2019 (see Note 5) will provide sufficient liquidity for more than a twelve-month period from the date of filing this Quarterly Report on Form 10-Q. 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 operations, including the commercialization of any of our drug candidates.

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 lease 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 lease standard will continue to be in accordance with ASC 840, “Leases” (“ASC 840”). An entity that elects this additional (and optional) transition method must provide the required ASC 840 disclosures for all periods that continue to be in accordance with ASC 840. The amendments do not change the existing disclosure requirements in ASC 840.

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. The Company adopted ASU 2018-11 on January 1, 2019 using a modified retrospective method and will not restate comparative periods. We elected the package of practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification and our assessment on whether a contract is or contains a lease. The adoption of this guidance resulted in the addition of material balances of right of use assets and lease liability to our consolidated balance sheets at January 1, 2019, primarily relating to our lease of office space (see Note 8). The impact to our consolidated statements of operations was not material as a result of this standard.

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. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements as of January 1, 2019. The adoption of ASU 2018-07 had no impact on nonemployee performance awards as they are measured based on the outcome that is probable.

Other pronouncements issued by the FASB or other authoritative accounting standards group 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 U.S. generally accepted accounting principles (“GAAP”) requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. Actual results could differ from those estimates. Such differences could be material to the financial statements.

Cash and Cash Equivalents

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

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of September 30, 2019 and December 31, 2018, we have approximately \$1.2 million 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 September 30, 2019 and December 31, 2018 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 are included in interest and other income (expense), net. Unrealized gains, if determined to be temporary, are included in accumulated other comprehensive income in equity. 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

Effective January 1, 2018, the Company began recognizing revenue under ASC Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), using the modified retrospective transition method. The impact of adopting the new revenue standard was not material to our consolidated financial statements and there was no adjustment to beginning retained earnings on January 1, 2018. The core principle of this new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606’s definition of a “distinct” good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

Research and Development Costs

Generally, research and development costs are expensed as incurred. Nonrefundable 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 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 condensed consolidated balance sheets includes, among other things, 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 September 30, 2019 and December 31, 2018, we recorded approximately \$7.0 million and \$9.7 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.

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

Stock-Based Compensation

We recognize all stock-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 stock-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.

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

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 periods presented or because such potentially dilutive securities were out of the money and the Company realized net income during the periods presented. The amounts of potentially dilutive securities excluded from the calculation were 8,060,758 and 5,230,922 for the three and nine months ended September 30, 2019 and 2018, respectively.

The following outstanding shares of potentially dilutive securities 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 Nine Months Ended September 30,	
	2019	2018
Unvested restricted stock	5,357,204	4,604,775
Stock options	2,539,540	610,000
Warrants	147,058	—
Shares issuable upon note conversion	16,956	16,147
Total	8,060,758	5,230,922

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.

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at September 30, 2019 and December 31, 2018:

(in thousands)	September 30, 2019	December 31, 2018
Checking and bank deposits	\$ 42,302	\$ 39,268
Money market funds	2,373	2,690
Total	\$ 44,675	\$ 41,958

NOTE 3 – INVESTMENT SECURITIES

Our investments as of September 30, 2019 and December 31, 2018 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at September 30, 2019 and December 31, 2018:

(in thousands)	September 30, 2019			
	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 October 2019 and September 2020) (held-to-maturity)	\$ 27,776	\$ 35	\$ 3	\$ 27,808
Total short-term investment securities	\$ 27,776	\$ 35	\$ 3	\$ 27,808
(in thousands)	December 31, 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 January	\$ 26,943	\$ 2	\$ 10	\$ 26,935

2019 and November 2019) (held-to-maturity)

Total short-term investment securities	<u>\$ 26,943</u>	<u>\$ 2</u>	<u>\$ 10</u>	<u>\$ 26,935</u>
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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 September 30, 2019 and December 31, 2018, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable, approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc.) 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 to the Ariston subsidiary including accrued and unpaid interest of the 5% Notes was approximately \$19.1 million at September 30, 2019 and \$18.4 million at December 31, 2018. No payments have been made on the 5% Notes since the merger and through September 30, 2019.

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 September 30, 2019 and December 31, 2018. 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 September 30, 2019 and December 31, 2018:

(in thousands)

	Financial liabilities at fair value as of September 30, 2019			
	Level 1	Level 2	Level 3	Total
5% Notes	\$ —	\$ —	\$ 95	\$ 95
Total	\$ —	\$ —	\$ 95	\$ 95

	Financial liabilities at fair value as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
5% Notes	\$ —	\$ —	\$ 67	\$ 67
Total	\$ —	\$ —	\$ 67	\$ 67

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

The Company’s financial instruments include cash, cash equivalents consisting of money market funds, accounts payable and debt. Cash, cash equivalents, accounts payable and debt are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature.

The following table summarizes the changes in Level 3 instruments during the nine months ended September 30, 2019:

(in thousands)

Fair value at December 31, 2018	\$	67
Interest accrued on face value of 5% Notes		690
Change in fair value of Level 3 liabilities		(662)
Fair value at September 30, 2019	\$	<u>95</u>

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 March 2019, we completed an underwritten public offering of 4,100,000 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 615,000 shares of common stock, which was exercised), at a price of \$5.87 per share. Proceeds from this offering, including the overallotment, after underwriting discounts and offering expenses were approximately \$27.5 million.

During the nine months ended September 30, 2019, we sold a total of 6,559,819 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately \$50.0 million at an average selling price of \$7.62 per share, resulting in net proceeds of approximately \$49.2 million after deducting commissions and other transactions costs.

Subsequent to the third quarter, from October 1, 2019 through November 12, 2019, we sold an aggregate of 3,641,346 shares of common stock pursuant to the 2017 ATM for aggregate total gross proceeds of approximately \$22.4 million at an average selling price of \$6.16 per share, resulting in net proceeds of approximately \$22.1 million after deducting commissions and other transactions costs.

The 2017 S-3 is currently our only active shelf registration statement. After deducting shares already sold there is approximately \$36.3 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. As of September 30, 2019, 6,857,207 shares of restricted stock and 2,539,540 options were outstanding and up to an additional 1,114,263 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. 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 following table summarizes stock option activity for the nine months ended September 30, 2019:

	Number of shares	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2018	1,916,900	\$ 6.50	9.75	\$ —
Granted	740,000	6.90		
Exercised	—	—		
Forfeited	(117,360)	6.25		
Expired	—	—		
Outstanding at September 30, 2019	<u>2,539,540</u>	<u>\$ 6.63</u>	<u>9.14</u>	<u>\$ 1,849,055</u>
Expected to vest at September 30, 2019	<u>2,539,540</u>	<u>\$ 6.63</u>	<u>9.14</u>	<u>\$ 1,849,055</u>
Exercisable at September 30, 2019	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>

Total expense associated with the stock options was approximately \$0.8 million and zero during the three months ended September 30, 2019 and 2018, respectively, and \$2.3 million and zero during the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, there was approximately \$3.4 million of total unrecognized compensation cost related to unvested time-based stock options, which is expected to be recognized over a weighted-average period of 1.72 years. As of September 30, 2019, the stock options outstanding include options granted to both employees and non-employees which are both time-based and milestone-based. Stock-based compensation for milestone-based options will be recorded if and when a milestone occurs.

The fair value of the Company’s option awards granted during the nine months ended September 30, 2019 and 2018 were estimated on the grant date using the Black-Scholes option-pricing model using the assumptions below:

	Nine months ended	
	September 30, 2019	September 30, 2018
Volatility	172.99-291.61	186.99-305.77
Expected term (in years)	5.0-6.25	5.0-6.25
Risk-free rate	1.96-2.49%	2.56-2.72%
Expected dividend yield	—%	—%

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 nine months ended September 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	6,095,692	\$ 8.07
Granted	1,586,520	12.95
Vested	(713,625)	9.21
Forfeited	(111,380)	7.84
Outstanding at September 30, 2019	<u>6,857,207</u>	<u>\$ 7.68</u>

Total expense associated with restricted stock grants was approximately \$1.3 million and \$(0.2) million during the three months ended September 30, 2019 and 2018, respectively, and \$3.4 million, and \$11.4 million during the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, there was approximately \$5.3 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. This amount does not include, as of September 30, 2019, 4,182,391 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones. Until the measurement date is reached for milestone awards, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the grant date.

Stock-Based Compensation

The following table summarizes stock-based compensation expense information about restricted stock and stock options for the three and nine months ended September 30, 2019:

(in thousands)	Three months ended September 30, 2019	Nine months ended September 30, 2019
Stock-based compensation expense associated with restricted stock	\$ 1,253	\$ 3,381
Stock-based compensation expense associated with option grants	822	2,333
Total	<u>\$ 2,075</u>	<u>\$ 5,714</u>

Warrants

The following table summarizes warrant activity for the nine months ended September 30, 2019:

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2018	—	\$ —	\$ —
Issued	147,058	4.08	
Exercised	—	—	
Expired	—	—	
Outstanding at September 30, 2019	<u>147,058</u>	<u>\$ 4.08</u>	<u>\$ 224,999</u>

There was no stock compensation expense related to warrants during the nine months ended September 30, 2019.

NOTE 6 – OTHER LIABILITIES

The following is a summary of Notes Payable included in other current liabilities on the Company's condensed consolidated balance sheet:

(in thousands)	September 30, 2019			December 31, 2018		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	\$ 95	\$ —	\$ 95	\$ 67	\$ —	\$ 67
Total	<u>\$ 95</u>	<u>\$ —</u>	<u>\$ 95</u>	<u>\$ 67</u>	<u>\$ —</u>	<u>\$ 67</u>

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 \$19.1 million at September 30, 2019 and \$18.4 million at December 31, 2018. No payments have been made on the 5% Notes as of September 30, 2019.

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).

Current Liabilities

In 2018, we entered into an agreement with a contract manufacturer for the clinical and potential commercial supply of one of our product candidates. As part of this agreement, the contract manufacturer has agreed to defer payment of certain costs and expenses under the agreement in exchange for the payment of an administrative fee. To date we have incurred expenses related to this agreement of approximately \$43.0 million as of September 30, 2019, which include both service fees and raw material costs. No payments have been made to the contract manufacturer as of September 30, 2019. Accordingly, as of September 30, 2019, \$43.0 million is included in current liabilities in the Company's unaudited condensed consolidated balance sheet, of which \$17.7 million, \$4.0 million and \$21.3 million are due in the first, second and third quarter of 2020, respectively. As of December 31, 2018, \$18.4 million is included in long-term liabilities in the Company's condensed consolidated balance sheet. We will incur an administrative fee of six percent (6%) per year starting from the date of invoice issuance. For the three and nine months ended September 30, 2019, we have accrued \$0.5 million in administrative fees in connection with these costs, which has been included in interest expense in the Company's unaudited condensed consolidated statements of operations.

NOTE 7 – LONG-TERM DEBT

On February 28, 2019 (the "Closing Date"), the Company ("Borrower") entered into a term loan facility of up to \$60.0 million ("Term Loan") with Hercules Capital, Inc., ("Hercules"), the proceeds of which will be used for its ongoing research and development programs and for general corporate purposes. The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the "Loan Agreement"), which provides for up to four separate advances. The first advance of \$30.0 million was drawn on the Closing Date. Two additional advances of \$10.0 million may be drawn at the Borrower's option but subject to the clinical trial milestones, and the fourth advance of \$10.0 million, available in minimum increments of \$5.0 million, is available through December 15, 2020 subject to the approval of Hercules' investment committee.

The Term Loan will mature on March 1, 2022 (the “Loan Maturity Date”). Each advance accrues interest at a per annum rate of interest equal to the greater of either (i) the “prime rate” as reported in The Wall Street Journal plus 4.75%, and (ii) 10.25%. The Term Loan provides for interest-only payments until October 1, 2020. The interest-only period may be extended to April 1, 2021 if the Borrower, on or before September 30, 2020, achieves either the third milestone or the Company has raised at least an amount equal to \$150.0 million in unrestricted net cash proceeds from one or more equity financings, subordinated indebtedness and/or upfront proceeds from business development transactions permitted under the Loan Agreement, in each case after February 7, 2019, and prior to September 30, 2020. Thereafter, amortization payments will be payable monthly in eighteen installments (or, if the period requiring interest-only payments has been extended to April 1, 2021, in twelve installments) of principal and interest (subject to recalculation upon a change in prime rates). At its option upon seven business days’ prior written notice to Hercules, the Company may prepay all or any portion greater than or equal to \$5.0 million of the outstanding advances by paying the entire principal balance (or portion thereof), all accrued and unpaid interest, subject to a prepayment charge of 3.0%, if such advance is prepaid in any of the first twelve months following the Closing Date, 1.5%, if such advance is prepaid after twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date, and 0% thereafter. In addition, an end of term charge equal to 3.25% of the aggregate principal amount of the loan extended by Hercules is due on the maturity date. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding.

The Term Loan is secured by a lien on substantially all of the assets of the Borrower, other than intellectual property and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. As of September 30, 2019, the Company has been in compliance with all covenants.

The events of default under the Loan Agreement include, without limitation, and subject to customary grace periods, (1) the Borrower’s failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) the Borrower’s breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse effect, (4) the Borrower making a false or misleading representation or warranty in any material respect, (5) the Borrower’s insolvency or bankruptcy, (6) certain attachments or judgments on the Borrower’s assets, or (7) the occurrence of any material default under certain agreements or obligations of the Borrower involving indebtedness in excess of \$750,000. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 2% of the total amount funded. A warrant (the “Warrant”) was issued by Borrower to Hercules to purchase 147,058 shares of common stock with an exercise price of \$4.08. The Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares will be registered and freely tradeable within six months of issuance. The Company accounted for the Warrant as an equity instrument since it was indexed to the Company’s common shares and met the criteria for classification in shareholders’ equity. The relative fair value of the Warrant on the date of issuance was approximately \$1.0 million and was treated as an offset to the Term Loan. This amount will be amortized to interest expense using the straight line method, which approximates the effective interest method, over the life of the Term Loan.

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

Exercise Price	\$	4.08
Common share price on date of issuance	\$	6.80
Volatility		195.9%
Risk-free interest rate		2.63%
Expected dividend yield		—%
Contractual term (in years)		7.00 years

The Company incurred financing expenses of \$2.8 million related to the Hercules Loan Agreement which are recorded as an offset to long-term debt on the Company’s condensed consolidated balance sheet. The debt issuance costs are being amortized over the term of the debt using the straight-line method, which approximates the effective interest method, and are included in interest expense in the Company’s unaudited condensed consolidated statements of operations. Amortization of debt issuance costs was \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2019, respectively. At September 30, 2019, the remaining unamortized balance of debt issuance costs were \$2.2 million.

Long-term debt as of as of September 30, 2019, is as follows (in thousands):

	September 30, 2019
Long-term debt	\$ 30,000
End of term fee	975
	<u>30,975</u>
Less: unamortized debt issuance costs	(2,234)
	<u>28,741</u>
Less: Current portion	—
Long-term debt– non-current	<u>\$ 28,741</u>

NOTE 8 – LEASES

In October 2014, we entered into an agreement (the “Office Agreement”) with Fortress Biotech, Inc. (“FBIO”) to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO, 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. At January 1, 2019 we recognized a lease liability and corresponding Right of Use (ROU) asset based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. The present values of our lease liability and corresponding ROU asset are \$10.7 million and \$8.5 million, respectively, as of September 30, 2019. Our leases have remaining lease terms of 1 year to 12 years. One lease has a renewal option to extend the lease for an additional term of 2 years.

The initial commitment period of the 45% rate is for a period of three (3) years. We and FBIO currently 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. Also in connection with this lease, in October 2014 we pledged \$0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying consolidated balance sheets. Additional collateral of \$0.6 million was pledged in April 2018 to increase the letter of credit for the office space.

The following components of lease expense are included in the Company’s condensed consolidated statements of operations for the three and nine months ended September 30, 2019:

(in thousands)	Three months ended, September 30, 2019	Nine months ended, September 30, 2019
Operating lease cost	\$ 1,065	\$ 2,058
Net lease cost	<u>\$ 1,065</u>	<u>\$ 2,058</u>

As of September 30, 2019, the weighted-average remaining operating lease term was 9.5 years and the weighted-average discount rate for operating leases was 10.25%. Cash paid for amounts included in the measurement of operating lease liabilities during the nine months ended September 30, 2019 was \$1.1 million.

The balance sheet classification of lease liabilities was as follows:

(in thousands)	September 30, 2019
Liabilities	
Lease liability – current portion	\$ 1,365
Lease liability – non-current	9,380
Total lease liability	<u>\$ 10,745</u>

As of September 30, 2019, the maturities of lease liabilities were as follows:

(in thousands)	<u>Operating leases</u>
Remainder of 2019	\$ 393
2020	1,551
2021	1,560
2022	1,586
2023	1,581
After 2023	12,061
Total lease payments	<u>18,732</u>
Less: Interest	(7,987)
Present value of lease liabilities(*)	<u>\$ 10,745</u>

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

NOTE 9 – LICENSE AGREEMENTS

TG-1101 (Ublituximab)

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

An upfront payment of \$2.0 million, which was received in December 2012, net of \$0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately \$38,000 for each of the three months ended September 30, 2019 and 2018, and \$114,000 for each of the nine months ended September 30, 2019 and 2018 and, at September 30, 2019 and December 31, 2018, have deferred revenue of approximately \$1.0 million and \$1.1 million, respectively, associated with this \$2 million payment (approximately \$152,000 of which has been classified in current liabilities at September 30, 2019 and December 31, 2018).

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

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co. (“Hengrui”), to acquire worldwide intellectual property rights, excluding Asia but including Japan, and for the research, development, manufacturing, and commercialization of products containing or comprising of any of Hengrui’s Bruton’s Tyrosine Kinase inhibitors containing the compounds of either TG-1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Pursuant to the agreement, in April 2018, we paid Jiangsu an upfront fee of \$1.0 million in our common stock recorded to noncash stock expense associated with in-licensing agreements in our condensed consolidated statement of operations. In addition, in July 2019, we paid Jiangsu the first milestone of \$0.1 million in our common stock recorded to noncash stock expense associated with in-licensing agreements in our consolidated statement of operations. 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 Novimmune an upfront payment of \$3.0 million in our common stock recorded to noncash stock expense associated with in-licensing agreements in our consolidated statement of operations. 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 10 – RELATED PARTY TRANSACTIONS

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. At January 1, 2019, we recognized a lease liability of \$9.3 million, with a corresponding Right of Use (ROU) asset of \$7.7 million based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. 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 build-out costs have been recorded in Leasehold Interest, net on the Company’s condensed consolidated balance sheets and will be amortized over the 15-year term of the Office Agreement. The initial commitment period of the 45% rate is for a period of three (3) years. We and FBIO currently 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. Also, in connection with this lease, in October 2014 we pledged \$0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying consolidated balance sheets. Additional collateral of \$0.6 million was pledged in April 2018 to increase the letter of credit for the office space.

In July 2015, we entered into a Shared Services Agreement (the “Shared Services Agreement”) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately \$0.6 million and \$1.4 million for shared services for the nine months ended September 30, 2019 and 2018, respectively, and expenses of approximately \$0.2 million for each of the three months ended September 30, 2019 and 2018, primarily related to shared personnel.

In March 2015, we entered into a Global Collaboration Agreement (“Collaboration Agreement”) with Checkpoint for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. The Collaboration Agreement was amended in June 2019 and upon execution of the amendment we incurred an upfront fee of \$1.0 million. We incurred expenses of approximately \$4.0 million and \$0.5 million for the nine months ended September 30, 2019 and 2018, respectively, and expenses of approximately \$2.7 million and \$0.1 million for the three months ended September 30, 2019 and 2018, the majority of which relates to manufacturing expenses of PD-L1. The relevant expenses are recorded in other research and development in the accompanying condensed consolidated statement of operations.

NOTE 11 – SUBSEQUENT EVENTS

In October 2019, we finalized a five-year lease for office space in New Jersey (the “NJ Lease”). We approximate an average annual rental obligation of \$0.3 million under the NJ Lease. We began to occupy this new space in October 2019, with rental payments beginning in November 2019.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contain 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, 2018.

OVERVIEW

We are a biopharmaceutical company dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL and NHL, with ublituximab also in pivotal trials for MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily inhibitor of PI3K delta. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K delta inhibitors. When used together in combination therapy, ublituximab and umbralisib are referred to as “U2”. Additionally, we have recently brought into Phase 1 clinical development TG-1501, an anti-PD-L1 monoclonal antibody, TG-1701, a covalently-bound Bruton’s Tyrosine Kinase (BTK) inhibitor, and TG-1801, an anti-CD47/CD19 bispecific antibody.

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.

OUR PRODUCTS UNDER DEVELOPMENT

We have leveraged our B-cell platform to develop a robust drug pipeline of both targeted orally available, potent and selective small molecule kinase inhibitors and intravenously delivered “off-the-shelf” immunotherapies that leverage the patient’s own immune system to fight cancer. We currently own worldwide development and commercial rights, subject to certain limited geographical restrictions, to all of our pre-clinical and clinical programs. The following table summarizes our most advanced drug candidates:

Clinical Drug Candidate (molecular target)	Initial Target Disease	Stage of Development (pivotal study)
Ublituximab/TG-1101 (anti-CD20/mAb)	Chronic Lymphocytic Leukemia	Phase 3 trial (UNITY-CLL)
	Relapsing Multiple Sclerosis	Phase 3 trials (ULTIMATE I and II)
Umbralisib/TGR-1202 (PI3K delta inhibitor)	Chronic Lymphocytic Leukemia	Phase 3 trial (UNITY-CLL)
	Marginal Zone Lymphoma	Phase 2b trial (UNITY-NHL)
	Follicular Lymphoma	Phase 2b trial (UNITY-NHL)
TG-1501 (anti-PDL1)	B-cell Cancers	Phase 1 trial
TG-1701 (BTK inhibitor)	B-cell Cancers	Phase 1 trial
TG-1801 (anti-CD47/CD19)	B-cell Cancers	Phase 1 trial

Phase 3 and Registration-Directed Clinical Trial Highlights

We have initiated and enrolled several Phase 3 and registration-directed Phase 2b clinical trials (i.e., clinical trials that may support a marketing application for approval). The following are the current Phase 3 trials and registration-directed Phase 2b clinical trials:

- **UNITY-NHL Phase 2b Trial:** UNITY-NHL is a broad Phase 2b registration-directed clinical trial designed to evaluate the efficacy and safety of umbralisib monotherapy and U2 combinations in patients with previously treated NHL. The marginal zone lymphoma (MZL) and the follicular lymphoma (FL)/small lymphocytic lymphoma (SLL) single agent umbralisib cohorts of this trial are fully enrolled. The primary objective of these cohorts is to assess the efficacy of single agent umbralisib as measured by Overall Response Rate (ORR).
- **UNITY-NHL MZL Single Agent Umbralisib Cohort:** The MZL cohort enrolled adult patients who had at least one prior line of therapy that included an anti-CD20 monoclonal antibody. In February 2019, we announced that the MZL cohort met the primary endpoint of ORR as determined by Independent Review Committee (IRC) for all treated patients (n=69). The results met our target guidance of 40-50% ORR. Interim safety and efficacy data from the MZL cohort were presented in an oral presentation at the American Association for Cancer Research (AACR) annual meeting on April 1, 2019. The data presented included safety and tolerability data on all 69 treated patients (safety population) and efficacy data on 42 patients who were enrolled at least 9 cycles (28 day cycles) prior to the data cut-off date (interim efficacy population). The safety population had a median duration of exposure of 6.9 months and no unexpected toxicities were observed. Analysis of the interim efficacy population showed an ORR by IRC of 52%, including 19% CR rate, an 88% clinical benefit rate by IRC (defined as patients obtaining Complete Response + Partial Response + Stable Disease) and a median duration of exposure of 10.1 months. These results were also presented in oral presentations during the 2019 American Society of Clinical Oncology (ASCO) annual meeting and the 2019 International Conference on Malignant Lymphoma (ICML) both held in June of 2019. Previously, in January 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to umbralisib for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen. The BTD was based on interim data from the MZL cohort of the UNITY-NHL trial. In April 2019, the FDA granted orphan drug designation to umbralisib for the treatment of patients with any of the three types of marginal zone lymphoma (MZL): nodal, extranodal, and splenic MZL. In June of 2019, we had a BTD meeting with the FDA to discuss the MZL submission strategy. Based on this meeting, we anticipate initiating a New Drug Application (NDA) submission for patients with previously treated MZL around year-end 2019.
- **UNITY-NHL FL/SLL Single Agent Umbralisib Cohort:** The FL/SLL cohort enrolled adult patients who had two or more prior lines of therapy that included an anti-CD20 monoclonal antibody and an alkylating agent. In October 2019, we announced that the FL patients within this cohort met the primary endpoint of ORR as determined by Independent Review Committee (IRC) for all treated follicular lymphoma patients (n=118). The results met our target guidance of 40-50% ORR. Importantly, umbralisib monotherapy appeared to be well tolerated with a safety profile consistent with previous reports. We plan to present the data at a future medical conference as well as discuss the data with the FDA.
- **UNITY-NHL Additional Cohorts:** There are additional exploratory cohorts of the UNITY-NHL trial focused on Diffuse Large B-Cell Lymphoma (DLBCL) and Mantle Cell Lymphoma (MCL). In total, there are currently four cohorts in the UNITY-NHL trial including, MZL, FL/SLL, DLBCL, and MCL. Each cohort is enrolled and evaluated separately from the others.
- **UNITY-CLL Phase 3 Trial Evaluating Umbralisib plus Ublituximab (U2):** UNITY-CLL is a global Phase 3 randomized controlled clinical trial comparing the U2 combination to an active control arm of obinutuzumab plus chlorambucil in patients with both treatment naïve and relapsed or refractory CLL. Two additional arms evaluating single agent ublituximab and single agent umbralisib were also enrolled for purposes of evaluating contribution in the U2 combination regimen. The primary endpoint for this study is progression free survival (PFS) which we intend to use to support a submission for approval of the U2 combination in CLL. The study completed enrollment in October 2017 with over 600 patients across the four treatment arms, with approximately 420 patients in the U2 and the active control arm combined. This trial is conducted under Special Protocol Assessment (SPA) with the FDA. In March 2019, the UNITY-CLL Data and Safety Monitoring Board (DSMB) conducted a pre-planned futility analysis of PFS. The DSMB determined that the trial was not futile and recommended the UNITY-CLL trial continue as planned. The pre-specified futility analysis of the UNITY-CLL trial did not allow for early stopping due to positive efficacy but only for lack of efficacy. The DSMB also reviewed safety information from all 600+ CLL patients on trial, including over 300 treatment naïve and previously treated patients on umbralisib alone or in combination with ublituximab. Based on its review, no safety concerns were identified and the DSMB recommended the UNITY-CLL trial continue without modification.
- **ULTIMATE I & II Trials Evaluating Single Agent Ublituximab in RMS:** ULTIMATE I and ULTIMATE II are two independent Phase 3 trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing ublituximab to teriflunomide in subjects with relapsing forms of Multiple Sclerosis (RMS). The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment which we intend to use to support a submission for approval of ublituximab in RMS. These trials are conducted under a SPA with the FDA. Full enrollment was completed in October of 2018, with approximately 1,100 subjects enrolled in both studies combined.

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 including clinical trial related expenses. 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 noncash compensation expenses as a result of the grants of restricted stock. Compensation expense for awards of 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.

We recognize all stock-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 stock-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.

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

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain diseases, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future, or at all. 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 medicines 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.

RESULTS OF OPERATIONS

Three months ended September 30, 2019 and 2018

License Revenue. License revenue was approximately \$38,000 for each of the three months ended September 30, 2019 and 2018. 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 Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$1.5 million for the three months ended September 30, 2019, as compared to \$0.6 million during the comparable period in 2018. The increase in noncash compensation expense was primarily due to noncash stock expense related to stock options during the period ended September 30, 2019.

Other Research and Development Expenses. Other research and development expenses increased by \$23.7 million to \$56.5 million for the three months ended September 30, 2019, as compared to \$32.8 million for the three months ended September 30, 2018. The increase in R&D expense is primarily attributable to ongoing late-stage clinical development programs and related manufacturing costs for ublituximab during the three months ended September 30, 2019. We expect our other research and development costs to decrease modestly for the remainder of 2019.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by \$1.4 million to \$0.6 million for the three months ended September 30, 2019, as compared to a credit of \$0.8 million for the three months ended September 30, 2018. The increase in noncash compensation expense was primarily related to greater compensation expense during the three months ended September 30, 2019 related to restricted stock granted to executive personnel due to a prior year credit for nonemployee awards

Other General and Administrative Expenses. Other general and administrative expenses was \$2.3 million for the three months ended September 30, 2019, as compared to \$1.8 million for the three months ended September 30, 2018. The increase was due primarily to 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 2019.

Interest Expense. Interest expense increased by \$1.3 million to \$1.5 million for the three months ended September 30, 2019, as compared to expense of \$0.2 million for the three months ended September 30, 2018. The increase is mainly due to the interest expense related to the Hercules financing agreement and the associated amortization of debt issuance costs for the three months ended September 30, 2019.

Other Income. Other income decreased by \$0.1 million to \$0.5 million for the three months ended September 30, 2019, as compared to \$0.6 million for the three months ended September 30, 2018. We expect our other income to remain at a comparable level for the remainder of 2019.

Nine months ended September 30, 2019 and 2018

License Revenue. License revenue was approximately \$0.1 million for each of the nine months ended September 30, 2019 and 2018. License revenue for the nine months ended September 30, 2019 and 2018 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 \$0.1 million for the nine months ended September 30, 2019, as compared to \$4.0 million during the comparable period in 2018. The expense during the nine months ended September 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.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$4.3 million for the nine months ended September 30, 2019, as compared to \$4.4 million during the comparable period in 2018.

Other Research and Development Expenses. Other research and development expenses increased by \$20.1 million to \$118.8 million for the nine months ended September 30, 2019, as compared to \$98.7 million for the nine months ended September 30, 2018. The increase in R&D expense is primarily attributable to ongoing late-stage clinical development programs and related manufacturing costs for ublituximab during the nine months ended September 30, 2019. We expect our other research and development costs to decrease modestly for the remainder of 2019.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants decreased by \$5.6 million to \$1.4 million for the nine months ended September 30, 2019, as compared to \$7.0 million for the nine months ended September 30, 2018. The decrease in noncash compensation expense was primarily related to greater compensation expense during the nine months ended September 30, 2018 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by \$0.4 million to \$6.6 million for the nine months ended September 30, 2019, as compared to \$6.2 million for the nine months ended September 30, 2018. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2019.

Interest Expense. Interest expense increased by \$2.7 million to \$3.4 million for the nine months ended September 30, 2019, as compared to expense of \$0.7 million for the nine months ended September 30, 2018. The increase is mainly due to the interest expense related to the Hercules financing agreement and the associated amortization of debt issuance costs for the nine months ended September 30, 2019.

Other Income. Other income decreased by \$0.1 million to \$1.2 million for the nine months ended September 30, 2019, as compared to \$1.3 million for the nine months ended September 30, 2018. We expect our other income to remain at a comparable level for the remainder of 2019.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of cash have been from the sale of equity securities, debt financings, the upfront payment from our Sublicense Agreement with Ildong, and warrant and option exercises. 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. 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 September 30, 2019, we had approximately \$72.5 million in cash and cash equivalents, and investment securities. We anticipate that our cash, cash equivalents, and investment securities on hand as of September 30, 2019, combined with the additional capital raised in the fourth quarter of 2019, will provide sufficient liquidity for more than a twelve-month period from the date of filing this Quarterly Report on Form 10-Q. 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 nine months ended September 30, 2019 was \$102.4 million as compared to \$95.2 million for the nine months ended September 30, 2018. The increase in cash used in operating activities was due primarily to increased expenditures associated with our ongoing clinical development programs and paydown of accounts payable and accrued expenses.

For the nine months ended September 30, 2019, net cash used in investing activities was \$0.7 million as compared to cash provided by investing activities of \$0.9 million for the nine months ended September 30, 2018. The decrease in net cash provided by investing activities was primarily due to the greater investment in treasury securities during the nine months ended September 30, 2019.

For the nine months ended September 30, 2019, net cash provided by financing activities of \$105.9 million related to the net proceeds from debt financings and net proceeds from the issuance of common stock as part of our 2017 ATM program and a public offering in March 2019.

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.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

As of September 30, 2019, we have known contractual obligations, commitments and contingencies of \$92.4 million related to our long-term debt, contract manufacturer and operating lease obligations.

Payment due by period (in thousands)

	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Contractual obligations					
Contract manufacturer	\$ 43,001	\$ 43,001	\$ —	\$ —	\$ —
Long-term debt	30,000	—	30,000	—	—
Operating leases	19,383	2,208	3,133	3,083	10,959
Total	<u>\$ 92,384</u>	<u>\$ 45,209</u>	<u>\$ 33,133</u>	<u>\$ 3,083</u>	<u>\$ 10,959</u>

The terms of certain of our licenses, royalties, development and collaboration agreements, as well as other research and development activities, require us to pay potential future milestone payments based on product development success. The above table excludes such obligations as the amount and timing of such obligations are unknown or uncertain.

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 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. Effective January 1, 2018, the Company began recognizing revenue under Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers (“ASC 606”), using the modified retrospective transition method. The impact of adopting the new revenue standard was not material to our consolidated financial statements and there was no adjustment to beginning retained earnings on January 1, 2018. The core principle of this new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606’s definition of a “distinct” good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

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

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.

Accounting For Income Taxes. In preparing our 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.

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 lease 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 lease standard will continue to be in accordance with ASC 840, “Leases” (“ASC 840”). An entity that elects this additional (and optional) transition method must provide the required ASC 840 disclosures for all periods that continue to be in accordance with ASC 840. The amendments do not change the existing disclosure requirements in ASC 840.

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. The Company adopted ASU 2018-11 on January 1, 2019 using a modified retrospective method and will not restate comparative periods. We elected the package of practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification and our assessment on whether a contract is or contains a lease. The adoption of this guidance resulted in the addition of material balances of right of use assets and lease liability to our consolidated balance sheets at January 1, 2019, primarily relating to our lease of office space (see Note 8). The impact to our consolidated statements of operations was not material as a result of this standard.

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. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements as of January 1, 2019. The adoption of ASU 2018-07 had no impact on nonemployee performance awards as they are measured based on the outcome that is probable.

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

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 September 30, 2019, our portfolio of financial instruments consists of cash equivalents, including bank deposits, and investments.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2019, 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 September 30, 2019, 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 September 30, 2019 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. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this Quarterly Report before making an investment in our securities.

Risks Related to Our Financial Position and Need for Additional Capital

We are a biopharmaceutical company with a limited operating history and have not generated any revenue from drug sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history on which investors can base an investment decision. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in January 2012. Our operations to date have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential drug candidates and undertaking pre-clinical studies and commencing clinical trials. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our drug candidates.

We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Since inception, we have focused substantially all of our efforts and financial resources on clinical trials and manufacturing of our drug candidates. To date, we have financed our operations primarily through public offerings of our common stock and a debt financing. Through November 8, 2019, we have received an aggregate of approximately \$550 million from such transactions. Approximately \$520 million of that amount constitute the aggregate gross proceeds from the sale of common stock in one or more offerings and through the use of our at the market sales program, or ATM. The remaining \$30.0 million is from our term loan facility with Hercules that we secured in February 2019.

Since inception, we have incurred significant operating losses. As of September 30, 2019, we had an accumulated deficit of \$661.6 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to significantly increase in connection with continuing our existing clinical trials and beginning additional clinical trials. In addition, if we obtain marketing approval for our drug candidates, we will incur significant sales, marketing and outsourced-manufacturing expenses. We also have incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate revenue.

To date, we have not generated any significant revenue from our drug candidates and we do not expect to generate any revenue from the sale of drugs in the near future. 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. Accordingly, we do not expect to generate significant and sustained revenue unless and until we obtain marketing approval of, and begin to sell umbralisib, ublituximab and/or one of our other product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- Successfully complete clinical trials that meet their clinical endpoints;
- Initiate and successfully complete all safety, pharmacokinetic, biodistribution, non-clinical studies required to obtain US and Foreign marketing approval for our drug candidates;
- Obtain approval from the US FDA and Foreign equivalent to market and sell our drug candidates;
- Establish commercial manufacturing capabilities alone and/or with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our drug candidates;
- Establish a commercial infrastructure to commercialize our drug candidates, if approved, by developing a sales force and/or entering into collaborations with third parties; and
- Achieve market acceptance of our drug candidates in the medical community and with third-party payors.

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 to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our drug development programs or commercialization efforts.

The development of pharmaceuticals is capital-intensive. We are currently advancing our most advanced drug candidates, umbralisib, ublituximab, TG-1501, TG-1701 and TG-1801 through clinical development. While we may experience short-term decreases in clinical trial expenses as our larger Phase 3 clinical trials complete and before our Phase 1 and 2 programs can advance into Phase 2 and 3, we do expect over time our overall expenses will increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate or continue clinical trials of, and seek marketing approval for, our drug candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Moreover, in anticipation of filing for regulatory approvals for umbralisib and ublituximab we will need to expend substantial resources on manufacturing and NDA/biologics license application (BLA) preparation over the next 12 to 24 months, which could exceed any cost savings associated with lower clinical trial expenses during the same period.

While this timing is our current estimate, 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.

As a result, significant additional funding will be required. Additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we 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, marketing and medical educational efforts that are required for a successful launch of umbralisib and/or ublituximab or any of our product candidates and otherwise forego attractive business opportunities.

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

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

Additionally, fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Dislocations in the financial markets have generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

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.

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

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for a product candidate could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing 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.

Risks Related to our Indebtedness

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

In February 2019, we entered into a Loan and Security Agreement (the “Loan Agreement”), with Hercules Capital, Inc., a Maryland corporation (“Hercules”) (See Note 7 to our condensed consolidated financial statements for more information). Under the Loan Agreement, Hercules will provide access to term loans with an aggregate principal amount of up to \$60.0 million (the “Term Loan”). Concurrently with the closing of the Loan Agreement, we borrowed an initial tranche of \$30.0 million. In addition, we have incurred short term liabilities of approximately \$43.0 million with a contract manufacturing organization (CMO) for the scale-up, tech-transfer, and long-term supply of one of our drug candidates. This is an expensive and lengthy process and we expect to incur additional obligations associated with these ongoing manufacturing activities over the course of the next 24 months, and potentially longer. To date, this CMO has provided payment terms which we believe are reasonable, however no assurance can be given that such terms will continue to be available to us in the future. No assurances can be made that the obligations associated with the Loan Agreement and the CMO will not have a material adverse impact on our financial condition.

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

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

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

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

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

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

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

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

Risks Related to Drug Development and Regulatory Approval

If we are unable to obtain regulatory approval for our most advanced drug candidates or other drug candidates and ultimately commercialize our most advanced drug candidates or other drug candidates, or experience significant delays in doing so, our business will be materially harmed.

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 a variety of reasons. We have substantially invested all of our efforts and financial resources in the identification and pre-clinical and clinical development of our drug candidates, including ublituximab, umbralisib, TG-1501, TG-1701 and TG-1801. Our ability to generate drug revenues, which we do not expect will occur for a number of years, if ever, will depend completely on the successful completion of our current and future Phase 3 and registration-directed clinical trials and commercialization of our drug candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. Each of our drug candidates will require additional non-clinical or clinical development, management of clinical, non-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining or manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from drug sales. The success of our most advanced drug candidates and other drug candidates will depend on several factors, including the following:

- Successful completion of our UNITY-NHL trial, UNITY-CLL trial and our ULTIMATE I and II trials;
- Receipt of regulatory approvals from applicable regulatory authorities for our drug candidates;
- Establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- Obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our drug candidates;
- Launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- Acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- Effectively differentiating and competing with other therapies;
- Obtaining and maintaining healthcare coverage and adequate reimbursement;
- Enforcing and defending intellectual property rights and claims; and
- Maintaining an acceptable safety profile of the drug candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business.

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 and we may not be able to continue our operations. 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 risks. The outcome of pre-clinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drug candidates. Once a drug candidate has displayed sufficient pre-clinical data to warrant clinical investigation, we will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

For instance, early clinical results seen with ublituximab (TG-1101) and/or umbralisib (TGR-1202) in a small number of patients may not be reproduced in expanded or larger clinical trials such as in our UNITY-CLL, UNITY-NHL and ULTIMATE I and II programs. Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. Larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region, or country to country basis which could materially adversely affect the study's outcome or the opinion of the validity of the study results by applicable regulatory agencies. In addition, 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. Clinical trial results can change over time as additional patients are added to a study or as additional follow-up is conducted, which may result in a material negative impact on the preliminary results. For instance, we recently announced that the Marginal Zone Lymphoma ("MZL") and the Follicular Lymphoma (FL) cohorts of the UNITY-NHL study met the primary endpoint of overall response rate (ORR), falling within our target range which was between 40%-50%, and while we believe that the ORR results have the potential to increase over time within this range, or beyond, as patients continue to be followed, no assurance can be given that this will be the case, and the results may ultimately fall at the lower end of the range. Further, time to event based endpoints such as duration of response (DOR) and progression free survival (PFS) have the potential to change, sometimes drastically, with longer follow-up. No assurance can be provided that the ORR, DOR and PFS data from the MZL and FL cohorts of the UNITY-NHL study will be supportive of an FDA approval or will support broad market uptake based on the profile of competitor drugs which may be available. While the MZL and FL cohorts of the UNITY-NHL study met their primary endpoint, each cohort of this study is operated and analyzed independently, and no assurance can be given that other cohorts from the UNITY-NHL study, including the MCL cohort, the DLBCL cohort, or the SLL patients enrolled within the FL/SLL cohort will meet their primary endpoint, have a positive outcome, or will be supportive of an FDA filing.

All of our Phase 3 and registration directed clinical trials such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II utilize international clinical research sites, including sites in eastern European countries. We work with what we believe are reputable CRO's and clinical research sites in conducting our studies internationally. Nevertheless, the risk of fraud, misconduct, incompetence, unexpected patient variability and other issues affecting the quality and the outcome of our Phase 3 and registration directed studies could arise from US or international sites. If that were to occur, the study could be negatively impacted, potentially even preventing it from being useful for regulatory approval. If such event were to occur, it would have a substantial negative impact on our business.

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. All of our current Phase 3 and registration directed studies such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II trials utilize blinded, independent, central review to assess the primary endpoint of such studies. If the results from interim analyses are not consistent with final results or results from our registration directed trials are different from the results found in the earlier studies of ublituximab and umbralisib, 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. For example, we recently presented to the FDA, interim results from the MZL cohort of our UNITY-NHL trial that supported the granting of Breakthrough Therapy Designation (BTD). These interim results were also presented at the 2019 American Association of Cancer Research (AACR) annual meeting, 2019 American Society of Clinical Oncology (ASCO) annual meeting, and the 2019 International Conference on Malignant Lymphoma (ICML). No assurance can be given that the final results from that cohort or FL cohort will reflect the activity seen in these interim results, or that the final results will be sufficient to file for accelerated approval for umbralisib for the treatment of MZL and FL, and if filed that umbralisib will receive accelerated approval. Similarly, while early Phase 1 data for umbralisib and ublituximab alone and together looked promising there is no assurance that the UNITY-CLL trial will be positive. Moreover, while we believe one of the key differentiators for umbralisib is its tolerability and side effect profile compared to other drugs in the same class, no assurance can be given that a differentiated safety and tolerability profile will be realized in our Phase 3 or registration directed trials such as UNITY-CLL or UNITY-NHL. Specifically, we have not yet assessed the final safety data from the MZL or FL cohorts of the UNITY-NHL study as patients continue on therapy, therefore there can be no assurance given that the final safety data, once fully analyzed, will be consistent with prior safety data presented on umbralisib, will be differentiated from other similar agents in the same class, or that it will be favorable enough to support an FDA filing. In addition, no assurance can be given that new toxicities, or an increase in the severity or frequency of previously seen toxicities, will not be observed, which could have a material negative impact on the approvability or marketability of umbralisib or any of our product candidates. Finally, while the Phase 2 data for ublituximab in MS looked promising, no assurance can be given that the profile will carry into Phase 3 and that the ULTIMATE I and II clinical trials will be positive.

In addition to umbralisib and ublituximab, we have a number of compounds in early clinical development, such as TG-1501, TG-1701 and TG-1801. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues, despite promising pre-clinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with umbralisib and/or ublituximab.

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

Our drug candidates umbralisib and ublituximab are in several Phase 3 and registration directed clinical trials such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II. As with all clinical trials, the risk of failure for our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Accordingly, our current Phase 3 and registration directed trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II and future clinical trials may not be successful.

Successful completion of our clinical trials is a prerequisite to submitting an NDA, or a BLA to the U.S. FDA and a Marketing Authorization Application (“MAA”), in the European Union for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether any of our clinical trials for our drug candidates will be completed on schedule, if at all.

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 research/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. We may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we may conduct that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including:

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- health authorities or institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or country;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or health authorities may require us, to conduct additional pre-clinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors, including our clinical trial sites, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or health authorities or IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, health authorities, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our drug candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the DSMB for such trial or by the FDA or other regulatory authorities. Such health authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. The DSMBs for the UNITY-CLL and UNITY-NHL studies meet regularly to review ongoing safety from these studies, in an unblinded manner if applicable, and may recommend modification to the study design or closure of the study entirely based on their interpretation of the benefit/risk of the study. While we develop charters that guide the nature of the DSMB's meetings, their analysis and interpretation of study data occurs independently from us and is wholly within their control. Even if the DSMB finds no safety concerns and recommends no modifications to our ongoing studies, this does not mean the safety profile of these studies may support a marketing approval. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. This could happen even for a protocol that has received an SPA. In September 2015, we announced a Phase 3 clinical trial for the combination of ublituximab plus umbralisib for patients with CLL, which is being conducted pursuant to an SPA with the FDA and in August 2017 we announced an SPA for our registration program for ublituximab in RMS. Many companies which have been granted SPAs 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, while changes or amendments to protocols are common during conduct of a clinical trial, protocol changes or amendments to a study 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. The FDA's willingness to agree to changes or amendments to a protocol or statistical analysis plan under SPA agreement is wholly within their discretion. Such re-reviews also provide an opportunity for the FDA to scrutinize any aspect of the study design and conduct, even if previously agreed to under the existing SPA. Failure to reach agreement with the FDA for routine protocol changes or modifications for any study we conduct under SPA could have a material negative impact to our ability to execute these studies. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. While UNITY-CLL is being operated in a blinded manner, it is an open label study; meaning that trial participants, investigators, site staff, some employees of our contract research organizations, and our field level employees (i.e. clinical research associates, monitors, etc.), among others, have knowledge of treatment arm assignments on a patient-level, which has the potential to introduce bias into study conduct. Further, while the ULTIMATE 1 and 2 clinical trials are double-blind, double-dummy studies, unblinding of treatment arm assignment may occur from time to time, for example, on the occurrence of unexpected safety events which may necessitate understanding of study treatment. While we believe we have put in place adequate firewalls to prevent inappropriate unblinding of study data consistent with standard industry practice for these types of studies, no assurance can be given that issues related to study conduct will not be raised. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the study design or data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

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. If we are required to repeat or conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. We may also incur additional costs if enrollment is increased. All of our current Phase 3 and registration-directed clinical trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II enrolled a larger number of patients than our initial projections, adding significant costs to those studies over and above what had been projected. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. 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. UNITY-CLL is an event-driven study, which means the study can only end when a certain pre-specified number of events have occurred. In the case of UNITY-CLL, an event is defined as disease progression or death. Given that these events cannot be predicted with certainty, predicting accurately when this study will reach a sufficient number of events to be complete is impossible. We have stated we believe the number of events can be reached by the end of 2019 or at some point in 2020 but there can be no assurance that this will occur and timelines for the completion of this study should not be relied upon given this inherent uncertainty. Delays beyond early 2020 could have a material and adverse impact on the Company. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. Any delays in our pre-clinical or future clinical development programs may harm our business, financial condition and prospects significantly.

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, or the FDA's willingness to accept such data, may be jeopardized.

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

We have and will continue to explore strategies for ublituximab and/or umbralisib that involve use of the FDA's accelerated approval pathway. Obtaining accelerated approval for an agent requires demonstration of meaningful benefit over all available therapies for a serious condition. 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. 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. We are currently awaiting final results from our UNITY-NHL trial, in particular the MZL and FL cohorts, which we are hoping will be useful for accelerated approval if positive. Even if the results are positive, no assurance can be given that umbralisib will obtain accelerated approval for a variety of reasons, including if a new treatment receives full approval prior to our potential receipt of accelerated approval. Previously, we were hopeful to utilize the results from our GENUINE study for accelerated approval but the intervening full approval of a drug called venetoclax for relapsed/refractory CLL has made that potential application

more challenging. While no final decision has been made as to the filing of the GENUINE study for accelerated approval, the Company is uncertain in regard to any filing at this time. We recently announced that final results from the GENUINE study demonstrated improved progression-free survival for the combination arm compared to ibrutinib alone. Despite this positive outcome, no assurance can be given that a filing based on the GENUINE results will ever be made, or if made would result in a favorable review by regulatory authorities.

Finally, if any of our drugs were ever 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.

Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

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

As is the case with all drugs, it is likely that there will be side effects associated with the use of our drug candidates. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound. Further, early clinical trials by their nature utilize a small sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate in Phase 3 or registration directed trials and on the market.

We are currently running our Phase 3 and registration-directed trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II and 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 the adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using ublituximab and umbralisib 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 health authorities and in the case of ublituximab and umbralisib, even if deemed acceptable for oncology and/or autoimmune indications, it may not be acceptable for diseases outside the oncology and autoimmune settings, 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 such as found in our on-going Phase 3 and registration-directed trials. Particularly, with respect to umbralisib, although over 1,000 patients to date have been dosed amongst all ongoing umbralisib studies, the full adverse effect profile of umbralisib is not known. As additional patients are exposed for longer durations to umbralisib, it is unknown whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as umbralisib 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. No assurance can be given that an acceptable safety and tolerability profile for umbralisib will continue to be demonstrated in the future with longer durations of exposure, at the fixed 800mg dose being evaluated in our registration-directed trials and in multiple drug combinations. 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 drug-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 ublituximab and umbralisib are being evaluated in combination with each other, 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. We also intend to explore multiple combination studies involving TG-1501, TG-1701, and TG-1801. 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 drug candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such drug candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drug candidates;
- regulatory authorities may require a more significant clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements, including warnings, contra-indications, or precautions, that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug candidates are distributed or administered, or to conduct additional clinical trials;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (“REMS”), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug candidates from the marketplace;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; 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 significantly impact our ability to successfully commercialize our drug candidates and generate revenues.

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.

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 a product candidate 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. 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 box warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a REMS requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in the 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 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 an indication;
- the FDA may not accept clinical data from trials 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 not approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for commercial supplies; 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.

A breakthrough therapy designation by the FDA for our drug candidates, including umbralisib for the treatment of adult patients with relapsed or refractory Marginal Zone Lymphoma who have received at least one prior treatment including an anti-CD20 monoclonal antibody, may not lead to a faster development or regulatory review or approval process, and it does not ensure that our drug candidates will receive marketing approval.

In January 2019, the FDA granted breakthrough therapy designation (also referred to as BTD) to umbralisib for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior treatment including an anti-CD20 monoclonal antibody. We may also seek breakthrough therapy designation for some of our other drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Our breakthrough therapy designation was based on interim data from the MZL cohort of the UNITY-NHL clinical trial. No assurance can be given that the full results from the MZL cohort of the UNITY-NHL clinical trial will be positive and support a filing for accelerated approval.

For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is wholly within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to grant such designation to the drug candidate. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation for some of our other drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we receive fast track designation for our other drug candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

While we have received orphan drug designation for umbralisib and ublituximab for specified indications, we may seek additional orphan drug designation for those and some of our other drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Ublituximab received orphan-drug designation from the FDA for the treatment of MZL (Nodal and Extranodal) in September 2013, for the treatment of CLL in August of 2010, and orphan-drug designation by the EMA for the treatment of CLL in November of 2009. We also obtained orphan drug designation for umbralisib as monotherapy for the treatment of CLL in August 2016 and all three types of MZL (nodal, extranodal and splenic) in April 2019, and in January 2017, we announced that the FDA granted Orphan Drug designation covering the combination of ublituximab and umbralisib for the treatment of patients with CLL and DLBCL. As part of our business strategy, we may seek orphan drug designation for our other drug candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek additional orphan drug designation for our other drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations.

As all of our product candidates are still under development, manufacturing site additions, scale-up 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 relatively small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity/ and analytical profile of the product candidates, which may affect the safety and efficacy of the products. For instance, the manufacturing process for ublituximab has undergone several process improvements during the clinical trial process which have resulted in analytical differences between the materials. Such process improvements continued during the conduct of Phase 3 and material from more than one manufacturing process were utilized in the Phase 3 UNITY-CLL trial. While analytical differences exist between those materials, we do not believe the differences will alter the safety or efficacy profile of ublituximab. However, it is possible that additional and/or different adverse events may appear among patients exposed to drug product manufactured under one process compared to the other, or that adverse events may arise with greater frequency, intensity and duration among patients exposed to drug product manufactured under one process compared to the other. Additionally, the efficacy of ublituximab also can be negatively impacted by such process changes. Given the uncertainty of the impact on product specifications, quality and performance, process improvements made during Phase 3 development carry a higher level of risk than those made prior to Phase 3 development. If there are significant differences in product attributes between the two materials, we may need to adjust our statistical analysis plans of the Phase 3 study to confirm that there is no difference in safety or efficacy between product made by each process in order to and allow us to utilize data from all enrolled patients, as well as be able to integrate clinical safety and/or efficacy results across studies to support any potential marketing application. There can be no assurance given that such analyses will be successful in demonstrating no clinical differences between these drug products, which could substantially impact the approvability of the U2 combination based on the results of the UNITY-CLL study. In such circumstances, that would have a material adverse effect on the Company.

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

In addition, we have engaged a secondary manufacturer for ublituximab to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for umbralisib to meet expanded clinical trial and commercial needs. 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. No assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to ublituximab or umbralisib as manufactured to date and used in currently available pre-clinical data and or in early clinical trials presented publicly or reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability.

In addition, as we move closer to commercialization for ublituximab and umbralisib we will need to scale-up production to ensure adequate commercial supply. We are currently in the process of scaling up ublituximab. This is an expensive process and there can be no assurance given that such scale-up will be successful in providing pharmaceutical product that is of sufficient quantity, or of a quality that is consistent with our previously established specifications, or that meets the requirements set by regulatory agencies under which we may seek approval of our product candidates. If scale-up were not to succeed our ability to supply our anticipated market at a reasonable cost of goods would be negatively impacted. In such event, that would have a material adverse effect on the Company. Scale up could also require additional process improvement that might be required to accommodate new and larger equipment utilized in the scaled-up process. If that were to occur and we could not demonstrate to the FDA that the materials were analytically substantially similar, we might be required to run additional clinical testing to demonstrate that they are substantially similar. That would entail a significant delay and significant increase in total cost, all of which would have a material adverse effect on the Company.

Risks Related to Commercialization

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and/or prevalence of CLL, relapsed/refractory MZL, relapsed/refractory FL and MS are unknown. 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. Our beliefs are typically based on one on one and group interactions with target physicians and our 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 total addressable market opportunity for umbralisib and ublituximab for the treatment of patients with CLL, MZL, FL and MS will ultimately depend upon, among other things, the final label indication, approval for sale for these indications, acceptance by the medical community, patient access, drug pricing and reimbursement. The number of patients in major markets, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, new patients may become increasingly difficult to identify or gain access to, or patients and physicians may choose to utilize competitive products, all of which would adversely affect our results of operations and our business.

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

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and 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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of any related companion diagnostic tests, the level of generic competition and the availability of reimbursement from government and other third-party payors.

For the cancer indications for which we are developing our products there are a number of established therapies with which we will compete:

- For the treatment of CLL, if U2 is approved, we expect U2 to compete with recently approved drugs such as ibrutinib (AbbVie and Janssen), venetoclax (AbbVie and Roche), obinutuzumab (Roche), idelalisib (Gilead) and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Additionally, there are two second generation BTK inhibitors similar to ibrutinib in late-stage clinical testing for CLL that could enter the market in the next 12-36 months. Each of these agents can be used as monotherapy or in combination with one or more of the other agents.
- For the treatment of Marginal Zone Lymphoma, if approved, we expect umbralisib to compete with ibrutinib (AbbVie and Janssen) and established treatments such as rituximab and several generically available chemotherapies. Additionally, the combination of rituximab and lenalidomide (Celgene) has recently been approved by the FDA for the treatment of relapsed MZL.
- For the treatment of Follicular Lymphoma, if approved, we expect umbralisib to compete with recently approved drugs such as obinutuzumab (Roche), idelalisib (Gilead), copanlisib (Bayer), and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Each of these agents can be used as monotherapy or in combination with one or more of the other agents. The combination of rituximab and lenalidomide (Celgene) has also been studied in FL and has recently been approved by the FDA for the treatment of relapsed FL. There are also several PI3K delta inhibitors in earlier stages of development.
- In addition, a number of pharmaceutical companies are developing antibodies and bispecific antibodies targeting CD20, CD19, CD47 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 U2 and umbralisib.

For Multiple Sclerosis for which we are developing ublituximab there are a number of established therapies with which we will compete:

- If ublituximab is approved, we expect ublituximab will primarily compete against other CD20 targeted agents, while the group of CD20 targeted agents will also compete broadly against a number of already approved MS therapies. Currently, there is one anti-CD20 monoclonal antibody approved, ocrelizumab (Roche), and another in Phase 3 development, ofatumumab (Novartis), which is expected to enter the market in the next 12-24 months.

TG-1501, TG-1701 and TG-1801 if approved will also face competition from drugs on the market and under development that have the same mechanism of action as each of those drugs.

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

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

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

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

We will face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and use of our drug candidates through compassionate use programs, and we will face an even greater risk if we commercially sell any drug candidates that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any drug candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage if we successfully commercialize any drug candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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 would also be necessary for commercial success. The degree of market acceptance of any approved product would depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- 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 the product candidate over alternative treatments;
- the safety of the product candidate in a broader patient group;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- changes in regulatory requirements by government authorities for the product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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.

Even if we are able to commercialize any drug candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and reimbursement for these drug candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the “ACA,” was enacted in 2010 and made significant changes to the United States’ healthcare system. 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, those 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.

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. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court’s prior decision. On December 14, 2018, Texas federal district court judge Reed O’Connor issued a ruling declaring that the ACA in its entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

The Bipartisan Budget Act of 2018, the “BBA,” which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019.

The 116th Congress has explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), have marked up legislation intended to address various elements of the prescription drug supply chain. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent “loopholes”, and efforts to cap the increase in drug prices. The House Energy and Commerce Committee approved drug-related legislation intended to increase transparency of drug prices and also curb anti-competitive behavior in the pharmaceutical supply chain. In addition, the House Ways & Means Committee approved legislation intended to improve drug price transparency, including for drug manufacturers to justify certain price increases. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services (“HHS”) finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to continue to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in “protected classes,” more transparency in the cost of drugs, including the beneficiary’s financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring that pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements. The proposal related to protected classes has been withdrawn and the disclosure requirements have been rejected by the courts. In addition, a proposed rule that would have passed drug rebates to consumers at the point of sale also has been withdrawn. However, it appears the Trump Administration will continue to explore its authority to make regulatory changes to the pharmaceutical industry. For example, the Trump Administration released an Advance Notice of Proposed Rulemaking related to an international price index model. It is unclear what eventually will be proposed, but the President has alluded to the concept of “most favored nation” pricing with regard to U.S. drug purchasing. In addition, HHS, in conjunction with the FDA, announced that it will be exploring a reimportation pathway in certain instances and for certain drugs.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits. The Trump Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the US Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There 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:

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the U.S. President has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a civilian hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze was to remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget (“OMB”) in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA’s responsiveness or in its ability to review submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion or at all. This hiring freeze was lifted later in 2017. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the “two-for-one” provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the “two-for-one” provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, on October 12, 2017, the President released an Executive Order intended to promote health care choices and competition and on June 24, 2019, the President released an Executive Order intended to improve price transparency and quality transparency. These may push HHS, FDA, and other relevant agencies to engage in rulemaking that may impact the pharmaceutical industry.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our drug candidates, we may not be successful in commercializing our drug candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sale, marketing or distribution of drugs. To achieve commercial success for any approved drug candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our drug candidates if and when they are approved.

In advance of FDA approval of our first product, we will need to make significant investments to build a commercial organization and infrastructure. We will need to hire a sales force and commercial support personnel, in order to build processes and systems to support a commercial launch prior to knowing whether our product will receive FDA approval. It is possible that the FDA approval is unexpectedly delayed or our product is not approved at all. In either case we will incur delays that may impede or significantly delay our ability to generate revenue and at the same time will incur significant expenses. If this were to occur, it would have a material adverse effect on the Company.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drug candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our drug candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing our drug candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our drug candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the Affordable Care Act require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

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.

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

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current Good Manufacturing Practice (“cGMP”) requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed, be subject to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety and/or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

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

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

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 ublituximab, umbralisib 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 ublituximab, umbralisib 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 ublituximab, umbralisib, or any future product candidates. We do not currently have an agreed upon brand name for umbralisib, and no assurance can be given that we will obtain one in a timely fashion. Any delay in obtaining a brand name for umbralisib or any other of our drug candidates could delay approval and/or commercialization and have a negative impact on our launch and future prospects for umbralisib or any other such drug candidates.

Risks Related to Our Dependence on Third Parties

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

In order to submit and maintain an Investigational New Drug application (“IND”), BLA, or NDA to the 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 portions of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. While we maintain an active IND for ublituximab and umbralisib enabling the conduct of studies in the FDA’s Division of Hematology and Oncology, and an active IND for ublituximab under the FDA’s Division of Neurology, there can be no assurance that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

Additionally, we use CRO’s to assist in the conduct of our current clinical trials and expect to use such services for future clinical trials and we rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and appropriate regulations. Our current and future CROs, investigators and other third parties play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product candidates. In addition to the third parties identified above, we are also heavily reliant on the conduct of our patients enrolled to our studies by our third-party investigators. We rely on our clinical trial sites and investigators to properly identify and screen qualified candidates for our clinical trials, and for them to ensure participants adhere to our clinical protocol requirements. The majority of our clinical trial conduct occurs in the out-patient setting, where patients are expected to continue to adhere to our study protocol specified requirements. The ability of our enrolled patients to properly identify, document, and report adverse events; take protocol specified study drugs at the correct quantity, time, and setting, as applicable; avoid contraindicated medications; and comply with other protocol specified procedures such as returning to the trial site for scheduled laboratory and disease assessments, is wholly out of our control. Deviations from protocol procedures, such as those identified previously, could materially affect the quality of our clinical trial data, and therefore ultimately affect our ability to develop and commercialize our drug candidates. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. If any of our clinical trial sites are required by the FDA or IRB to close down due to data management or patient management or any other issues we may lose patients. In our MS Phase 2 trial, during routine monitoring and site audits, significant Good Clinical Practice (GCP) violations and other noncompliance issues were identified at one of our US-based large academic sites. The investigator left the institution and shortly thereafter the site terminated their participation in our study before all data could be source document verified. While we do not believe this will have any effect on the overall results of the MS Phase 2 trial, sensitivity analyses excluding data from this site will be performed and no assurance can be given that the results were not affected.

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

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

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

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

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

We contract with third parties for the manufacture of our drug candidates for pre-clinical development and clinical trials, and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for pre-clinical development and clinical testing, as well as for the commercial manufacture of our drugs if any of our drug candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our drug candidates.

We do not have any long-term supply agreements with all our contract manufacturers. We purchase our required drug supply, including the drug product and drug substance on a purchase order basis. In addition, we may be unable to establish or maintain any agreements with third-party manufacturers or to do so on acceptable terms. 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.

Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

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

Moreover, our current long-term supply agreements and, we would expect all future long-term supply agreements would contain certain minimum purchases in what are commonly referred to as “take or pay” provisions. To the extent our demand does not meet the minimum supply required amounts, we would be forced to pay more than desired. This could create a situation where we are spending more than required and could impact our on-going operations and entail curtailing other important research and development or commercialization efforts. All of which could have a material adverse effect on the Company.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates or drugs could result in significant delays or gaps in availability of such drug candidates or drugs and may adversely affect our future profit margins and our ability to commercialize any drugs 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.

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 fill/finish suppliers, and 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.

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

The API, drug product and drug substance used in our drug candidates are currently supplied to us from single-source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. If any of our suppliers ceases its operations for any reason or is unable or unwilling to supply API, drug product, drug substance and other materials in sufficient quantities or on the timelines necessary to meet our needs, it could significantly and adversely affect our business, the supply of our drug candidates and our financial condition.

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. Various raw materials, components, and testing services required for our products may also be single sourced. 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 of 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.

For all of our drug candidates, we plan to identify and qualify additional manufacturers and other suppliers to provide such API, drug product and drug substance prior to or following submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and drug substance used in our drug candidates, if required, may not be accomplished quickly or at all. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and drug substance used in our drug candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

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.

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

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

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug 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 drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

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

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

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable drug candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any termination or expiration of any future collaboration agreement could adversely affect us financially or harm our business reputation.

Risks Relating to Our Intellectual Property

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

Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to 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 and intellectual property position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures.

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

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

Currently, the composition of matter patent for ublituximab and umbralisib are granted in both the United States and EU, among other countries. A method of use patent covering the combination of ublituximab and umbralisib has also been granted in the US, EU, Japan, and several other territories. Additionally, several method of use patents for ublituximab and umbralisib in various indications and settings have also 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. There can be no guarantee that any patents for which an application has already been filed, nor any patents filed in the future, for our TG-1501, TG-1701 and TG-1801 or for our pre-clinical 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, or what the scope of an issued patent may ultimately be.

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 file new patent applications or 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.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to some of the pending patent applications covering our drug candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, have been significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or we fail to appropriately prosecute and maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, 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 impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability, which would have a material adverse effect on our financial condition and results of operations. Furthermore, should we enter into other collaborations, including out-licensing or partnerships, 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.

In addition, U.S. patent laws may change, which could prevent or limit us or our subsidiaries from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include 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.

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.

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

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

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

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

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

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

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

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

Our competitors or other third parties may assert infringement claims against us, alleging that our drugs are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product 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.

We are aware of certain patents that may pose issues for our commercialization of our drug candidates. For example, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the United States which are expected to expire in November of 2019. 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 valid and enforced at the time we are intending to launch ublituximab, 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 decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, as courts or patent offices in the United States and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we are unable to do so, we may be forced to delay the launch of ublituximab or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

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

No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering 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. For example, we engage extensively with third parties, including academic institutions, to conduct non-clinical and clinical research on our product candidates. While we seek to ensure all material transfer and service agreements governing this research provide us with favorable terms covering newly generated intellectual property, a general principle under which much of this research with academic institutions is conducted provides third party ownership of newly generated intellectual property, with an exclusive option available for us to obtain a license to such intellectual property. Through the conduct of this research, it is possible that valuable intellectual property could be developed by a third party, which we will then need to license in order to better develop or commercialize our products. No assurance can be given that we will be able to successfully negotiate such a license on commercially reasonable terms, or at all. Further, should we fail to successfully negotiate a license to such intellectual property, most institutions are then free to license such intellectual property to any other third party, including potentially direct competitors of ours. Should we fail to adequately secure a license to any newly generated intellectual property, our ability to successfully develop or commercialize our products may be hindered, possibly materially.

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 invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the USPTO to institute inter parties review against the asserted patents, which may lead to a finding that all or some of the claims of the 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 pending patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

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

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

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

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

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

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

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

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

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

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

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

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

We expect to continue hiring qualified development personnel. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will be critical to our success. The loss of the services of our chief executive officer or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified medical and scientific personnel. 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.

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

As of November 2, 2019, we had 120 full-time employees, and we expect to continue to increase our number of employees and expand the scope of our operations. Our management and medical and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. To accommodate growth, additional physical expansion of our operations in the future may lead to significant costs, including capital expenditures, and may divert financial resources from other projects, such as the development of our drug candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our business.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Following its June 23, 2016 vote to leave the European Union, on March 29, 2017, the United Kingdom invoked Article 50 of the Lisbon Treaty and formally began the process of exiting the European Union. Although Brexit has already and may continue to adversely affect European and/or worldwide economic or market, political or regulatory conditions and may contribute to instability in the global financial markets, political institutions and regulatory agencies, the resulting immediate changes in foreign currency exchange rates have had a limited overall impact due to natural hedging. The long-term impact of Brexit, including on our business and our industry, will depend on the terms that are negotiated in relation to the United Kingdom's future relationship with the European Union, and we are closely monitoring the Brexit developments in order to determine, quantify and proactively address changes as they become clear. Despite the Brexit developments, we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or drug candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our drug candidates could be delayed.

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

On December 22, 2017, legislation commonly referred to as the "Tax 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, 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 and Being a Publicly-Traded Company

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

The trading price of our common stock 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 by us.

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

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

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

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

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, under the Loan Agreement, we are currently restricted from paying cash dividends, and we expect these restrictions to continue in the future. In addition, the terms of any future debt agreements may continue to preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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.

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

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

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

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline.

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

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

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

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

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2018, we had federal net operating loss carryforwards of approximately \$550.6 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. In addition, pursuant to the TCJA, we may not use net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. These new rules apply regardless of the occurrence of an ownership change.

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

- 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 November 12, 2019.
- 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 November 12, 2019.
- 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 November 12, 2019.
- 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 November 12, 2019.
- 101 The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Stockholders' (Deficit) Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).

*Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

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: November 12, 2019

By: /s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

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: November 12, 2019

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Chief Executive Officer and President

Principal Executive Officer

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: November 12, 2019

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

**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 September 30, 2019 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: November 12, 2019

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Chief Executive Officer and President

Principal Executive Officer

**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 September 30, 2019 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: November 12, 2019

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer