Table of Contents

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, 2021

OR

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

For the transition period from to

Commission File Number 001-32639

TG THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**36-3898269**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

(212) 554-4484
(Registrants telephone number, including area code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 ☐ 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 142,943,139 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 3, 2021.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED September 30, 2021

TABLE OF CONTENTS

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 ability to establish and maintain a commercial infrastructure and to successfully launch, market and sell UKONIQ® (umbralisib) in the U.S. and any products for which we obtain regulatory approval in the future;
- the success of the ongoing commercialization of UKONIQ and potential commercialization of any future products, including the anticipated rate and degree of market acceptance and pricing and reimbursement;
- the timing of and our ability to complete regulatory submissions for our product candidates and additional indications for UKONIQ, and acceptance and review of those submissions by regulatory authorities, including those in the U.S. and in additional geographies;
- our ability to obtain and maintain regulatory approvals for our product candidates, including ublituximab in combination with UKONIQ in chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) and ublituximab in relapsing forms of multiple sclerosis (RMS);
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, including, without limitation, UNITY-CLL Phase 3 clinical trial, ULTIMATE I and II Phase 3 clinical trials, UNITY-NHL Phase 2b clinical trial, and ULTRA-V Phase 3 clinical trial;
- our ability to advance drug candidates into, and successfully complete, clinical trials;
- our ability to establish and maintain contractual relationships, on commercially reasonable terms, with third parties for manufacturing, distribution and supply, and a range of other support functions for our clinical development and commercialization efforts;
- the implementation of our business model, strategic plans for our business, drug candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and product candidates;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations and enter into strategic arrangements, if desired;
- our ability to meet any of our financial projections or guidance, including without limitation short and long-term revenue projections or guidance and changes to the assumptions underlying those projections or guidance;
- our financial performance and cash burn management; and
- developments relating to our competitors and our industry.

SUMMARY RISK FACTORS

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

Risks Related to Commercialization

- We have limited experience as a commercial company, and the marketing and sale of UKONIQ or any future approved products may be less successful than anticipated or unsuccessful.
- The COVID-19 pandemic and related response measures to control it have impacted our sales and marketing efforts for UKONIQ and could have an adverse impact on our commercial launch of ublituximab, if approved.
- If UKONIQ or any future approved product does not achieve broad market acceptance among physicians, patients, payors, and the medical community, the revenues that we generate from product sales will be limited.
- If the market opportunities for UKONIQ and future approved products are smaller than we estimate or if any approval that we obtain is based on a narrower patient population, our revenue will be adversely affected.
- 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.
- If we are unable to establish additional commercial capabilities and infrastructure, we may be unable to generate sufficient revenue to sustain our business.
- Product liability lawsuits could cause us to incur substantial liabilities and limit commercialization of any of our products.

Risks Related to our Financial Position and Need for Additional Capital

- We have incurred significant operating losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- We will need to raise substantial additional funding. If we are unable to raise capital when needed, we will be forced to delay, reduce, or eliminate some of our drug development programs or commercialization efforts.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

Risks Related to Drug Development and Regulatory Approval

- If we are unable to obtain regulatory approval for our product candidates and ultimately cannot commercialize one or more of them, or experience significant delays in doing so, our business will be materially harmed. No assurance can be given that the U2 combination will be approved for any indication, including without limitation, treatment naïve and/or relapsed/refractory CLL/small lymphocytic lymphoma (SLL) or that ublituximab will be approved for the treatment of relapsing forms of multiple sclerosis. In addition, our business will also be materially harmed if we are unable to maintain approval of any products for which we receive approval, including UKONIQ, which received accelerated approval from the U.S. Food and Drug Administration (FDA) for patients with marginal zone lymphoma and follicular lymphoma. Continued approval for these indications is contingent upon verification and description of clinical benefit in a confirmatory trial.
- Our products and product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or significantly limit their commercial profile following marketing approval, if any.
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials. Moreover, interim, “top-line,” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed.
- Any 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. Although we have received orphan drug designation for UKONIQ and for some of our drug candidates for specified indications and may seek additional orphan drug designations, we may be unsuccessful in obtaining or maintaining the benefits associated with orphan drug status.

Risks Related to Governmental Regulation of the Pharmaceutical Industry

- We are subject to extensive regulation, including new legislation, regulatory proposals and third-party payor initiatives, that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.
- If we fail to comply with various healthcare laws and regulations, we may incur losses or be subject to liability.
- If we fail to comply with regulatory requirements, any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties.

Risks Related to our Dependence on Third Parties

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

Risks Related to Intellectual Property

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

Risks Related to COVID-19

- Public health issues, and specifically the pandemic caused by COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.

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

- We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion.
- Our ability to continue our clinical development and commercialization activities will depend on our ability to attract and maintain key management and other personnel.
- Certain of our executive officers, directors and other stockholders own more than 10% of our outstanding common stock and may be able to influence our management and the outcome of matters submitted to shareholders for approval.
- Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition more difficult, which could limit the price investors might be willing to pay for our common stock.
- Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit and could subject us to securities and shareholder derivative litigation.

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2021 (Unaudited)	December 31, 2020 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 326,512	$ 553,439
Short-term investment securities	30,338	51,987
Accounts receivable, net	1,384	—
Prepaid research and development	11,043	5,231
Other current assets	2,502	1,083
Total current assets	371,779	611,740
Restricted cash	1,263	1,259
Long-term investment securities	24,550	—
Right of use assets	8,804	9,312
Leasehold interest, net	1,892	2,051
Equipment, net	600	481
Goodwill	799	799
Total assets	$ 409,687	$ 625,642
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 44,702	$ 37,014
Other current liabilities	12,628	18,236
Loan payable – current portion	15,999	22,179
Lease liability – current portion	1,468	1,669
Accrued compensation	12,858	8,456
Total current liabilities	87,655	87,554
Deferred revenue, net of current portion	495	610
Loan payable – non-current	-	7,716
Lease liability – non-current	10,020	10,412
Total liabilities	98,170	106,292
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value per share (175,000,000 shares authorized, 142,984,448 and 140,617,606 shares issued, 142,943,139 and 140,576,297 shares outstanding at September 30, 2021 and December 31, 2020, respectively)	143	141
Additional paid-in capital	1,546,967	1,500,040
Treasury stock, at cost, 41,309 shares at September 30, 2021 and December 31, 2020	(234)	(234)
Accumulated deficit	(1,235,359)	(980,597)
Total stockholders' equity	311,517	519,350
Total liabilities and stockholders' equity	$ 409,687	$ 625,642

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	$ 1,992	$ —	$ 4,254	$ —
License revenue	38	38	114	114
Total revenue	$ 2,030	$ 38	$ 4,368	$ 114
Costs and expenses:				
Cost of product revenue	292	—	580	—
Research and development:				
Noncash compensation	4,534	4,618	19,061	8,150
Other research and development	47,433	45,846	140,872	114,785
Total research and development	51,967	50,464	159,933	122,935
Selling, general and administrative:				
Noncash compensation	9,463	23,712	27,857	38,618
Other selling, general and administrative	25,436	11,584	67,821	25,373
Total selling, general and administrative	34,899	35,296	95,678	63,991
Total costs and expenses	87,158	85,760	256,191	186,926
Operating loss	(85,128)	(85,722)	(251,823)	(186,812)
Other expense (income):				
Interest expense	1,038	1,610	4,559	5,038
Other income	(529)	(169)	(1,619)	(687)
Total other expense (income), net	509	1,441	2,940	4,351
Net loss	$ (85,637)	$ (87,163)	$ (254,763)	$ (191,163)
Basic and diluted net loss per common share	$ (0.65)	$ (0.73)	$ (1.93)	$ (1.70)
Weighted-average shares used in computing basic and diluted net loss per common share	132,353,119	119,176,336	132,109,912	112,380,784

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

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

	Common Stock		Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2021	140,617,606	$ 141	$ 1,500,040	41,309	$ (234)	$ (980,597)	$ 519,350
Issuance of common stock in connection with exercise of options	31,245	*	128	—	—	—	128
Issuance of restricted stock	893,488	1	(1)	—	—	—	—
Warrants issued with debt financing							—
Forfeiture of restricted stock	(21,643)	*	*	—	—	—	—
Issuance of common stock in public offering (net of offering costs of $0.2 million)	—	—	—	—	—	—	—
Offering costs paid	—	—	(183)	—	—	—	(183)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	16,618	—	—	—	16,618
Net loss	—	—	—	—	—	(90,628)	(90,628)
Balance at March 31, 2021	141,520,696	142	1,516,602	41,309	(234)	(1,071,225)	445,285
Issuance of common stock in connection with exercise of options	9,364	*	38	—	—	—	38
Issuance of common stock in connection with conversion of notes payable	—	—	—	—	—	—	—
Issuance of restricted stock	1,356,151	1	(1)	—	—	—	—
Forfeiture of restricted stock	(12,416)	*	*	—	—	—	—
Issuance of common stock in public offering (net of offering costs of $10.9 million)	—	—	—	—	—	—	—
Issuance of common stock in At-the-Market offerings (net of offering costs of $1.4 million)	—	—	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	16,304	—	—	—	16,304
Net loss	—	—	—	—	—	(78,497)	(78,497)
Balance at June 30, 2021	142,873,795	143	1,532,943	41,309	(234)	(1,149,722)	383,130
Issuance of common stock in connection with exercise of options	12,085		50	—	—	—	50
Issuance of restricted stock	214,223	*	*	—	—	—	—
Forfeiture of restricted stock	(115,655)	*	*	—	—	—	—
Offering costs paid	—	—	(22)				(22)
Compensation in respect of restricted stock and options granted to employees, directors and consultants	—	—	13,996	—	—	—	13,996
Net loss	—	—	—	—	—	(85,637)	(85,637)
Balance at September 30, 2021	142,984,448	$ 143	$ 1,546,967	41,309	$ (234)	$ (1,235,359)	$ 311,517

**Amount less than one thousand dollars*

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

	Common Stock		Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2020	109,425,243	$ 109	$ 739,956	41,309	$ (234)	$ (701,216)	$ 38,615
Issuance of common stock in connection with exercise of options	19,750	*	80	—	—	—	80
Issuance of restricted stock	774,300	1	(1)	—	—	—	—
Forfeiture of restricted stock	(10,000)	*	*	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	11,068	—	—	—	11,068
Net loss	—	—	—	—	—	(51,116)	(51,116)
Net loss	—	—	—	—	—	(51,116)	(51,116)
Balance at March 31, 2020	110,209,293	110	751,103	41,309	(234)	(752,332)	(1,353)
Issuance of common stock in connection with exercise of options	3,750	—	16	—	—	—	16
Issuance of restricted stock	2,208,529	2	(2)	—	—	—	—
Forfeiture of restricted stock	(41,666)	*	—	—	—	—	—
Issuance of common stock in public offering	9,775,000	10	165,032	—	—	—	165,042
Issuance of common stock in At-the-Market offerings (net of offering costs of $0.5 million)	4,535,608	5	76,031	—	—	—	76,036
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	7,370	—	—	—	7,370
Net loss	—	—	—	—	—	(52,884)	(52,884)
Balance at June 30, 2020	126,690,514	127	999,550	41,309	(234)	(805,216)	194,227
Issuance of common stock in connection with exercise of options	9,347	—	38	—	—	—	38
Issuance of restricted stock	915,000	1	(1)	—	—	—	—
Forfeiture of restricted stock	(65,000)	*	—	—	—	—	—
Issuance of common stock in offerings (net of offering costs of $10.9 million)	—	—	(1)	—	—	—	(1)
Issuance of common stock in At-the-Market offerings (net of offering costs of $2.0 million)	1,410,000	1	35,226	—	—	—	35,227
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	28,330	—	—	—	28,330
Net loss	—	—	—	—	—	(87,163)	(87,163)
Balance at September 30, 2020	128,959,861	$ 129	$ 1,063,142	41,309	$ (234)	$ (892,379)	$ 170,658

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

	Nine months ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (254,763)	$ (191,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	46,918	46,768
Depreciation and amortization	202	105
Amortization of premium on investment securities	421	(75)
Amortization of debt issuance costs	694	694
Amortization of leasehold interest	159	163
Noncash change in lease liability and right of use asset	1,422	1,364
Change in fair value of notes payable	(315)	286
Changes in assets and liabilities:		
(Increase) decrease in other current assets	(7,255)	2,503
Increase in accounts receivable	(1,384)	—
Increase in accounts payable and accrued expenses	12,090	5,893
Decrease in lease liabilities	(1,507)	(1,360)
Decrease in other current liabilities	(5,293)	(27,545)
Decrease in deferred revenue	(114)	(114)
Net cash used in operating activities	(208,725)	(162,481)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of short-term securities	40,000	35,250
Investment in held-to-maturity securities	(43,299)	(7,482)
Purchases of PPE	(321)	(202)
Net cash (used in) provided by investing activities	(3,620)	27,566
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of loan payable	(14,590)	—
Proceeds from sale of common stock, net	—	276,303
Proceeds from exercise of options	216	135
Offering costs paid	(204)	—
Net cash (used in) provided by financing activities	(14,578)	276,438
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(226,923)	141,523
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	554,698	113,888
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 327,775	$ 255,411
Reconciliation to amounts on consolidated balance sheets:		
Cash and cash equivalents	$ 326,512	$ 254,154
Restricted cash	1,263	1,257
Total cash, cash equivalents and restricted cash	$ 327,775	$ 255,411
Cash paid for:		
Interest	$ 2,698	$ 3,447

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 on a consolidated basis.

NOTE 1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

TG Therapeutics is a fully integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines across these therapeutic areas, UKONIQ received accelerated approval from the FDA for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20-based regimen and adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapies. Currently, we have three programs in Phase 3 development for the treatment of patients with RMS and patients with CLL and several investigational medicines in Phase 1 clinical development. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (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, 2020. The accompanying condensed December 31, 2020 balance sheet has been derived from these statements. The results of operations for the three and nine months ended September 30, 2021 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. (TG AUS), 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 activities of TG AUS result in immaterial currency translation adjustments and, thus, are included in Other Income/Expense on the Company's condensed consolidated statement of operations. The accompanying condensed 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 and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of September 30, 2021, we have an accumulated deficit of $1.2 billion.

Our major sources of cash have been proceeds from private placements and public offerings of equity securities. In February of 2021, umbralisib, now referred to as UKONIQ, was granted accelerated approval in the United States for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapy. Commercial sales of UKONIQ commenced in the first quarter of 2021. We have generated limited revenues to date from product sales. Even with the commercialization of UKONIQ and the potential future commercialization of our other drug candidates, we may not meet revenue guidance or become profitable. Our ability to achieve profitability depends on many factors, including our ability to generate revenue, our ability to obtain regulatory approvals for our drug candidates, our ability to successfully complete any post-approval regulatory obligations and our ability to successfully commercialize

our drug candidates. We may continue to incur substantial operating losses even as we begin to generate revenues from our drug candidates.

As of September 30, 2021, we had $381.4 million in cash and cash equivalents, and investment securities. We anticipate that our cash and cash equivalents, and investment securities as of September 30, 2021 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, our UKONIQ commercialization efforts, preparations for the potential commercialization of our other drug candidates, and 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 ongoing and future operations, including the commercialization of any of our drug candidates.

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

Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our 2020 Annual Report on Form 10-K, except as it relates to revenue recognition, accounts receivable, inventory, cost of product revenue, and the adoption of new accounting standards during the nine months ended September 30, 2021, as discussed below.

Revenue Recognition

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

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

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

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

Chargebacks and Administrative Fees: Chargebacks for discounts represent the Company's estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list prices charged to the customers who directly purchase the product from the Company. The customers charge the Company for the difference between what the customers pay the Company for the product and the customers' ultimate contractually committed or government required lower selling price to the qualified healthcare providers. As part of the Company's contractual commitments to sell product to qualified healthcare providers, the Company pays fees for administrative services, such as account management and data reporting.

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

GPO and Payor Rebates: the Company contracts with various private payor organizations and group purchasing organizations (GPO), primarily insurance companies, pharmacy benefit managers and clinics, for the payment of rebates with respect to utilization of our product. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

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

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

Subject to certain limitations, the Company's return policy allows for eligible returns of UKONIQ for credit under the following circumstances:

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

As of September 30, 2021, the Company has not received any returns.

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

Accounts Receivable

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns and chargebacks. Our contracts with customers have standard payment terms. We analyze accounts that are past due for collectability, and regularly evaluate the creditworthiness of our customers so that we can properly assess and respond to changes in their credit profiles. As of September 30, 2021, we determined an allowance for

expected credit losses related to outstanding accounts receivable was currently not required based upon our review of contractual payment terms and individual customer circumstances.

Cost of Product Revenue

Cost of product revenue consists primarily of materials and third-party manufacturing costs, as well as freight and royalties owed to our licensing partner for UKONIQ sales. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, the manufacturing costs of UKONIQ units recognized as revenue during the three and nine months ended September 30, 2021 were expensed prior to receipt of FDA approval on February 5, 2021, and therefore are not included in costs of product revenue during the current period.

Inventory

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

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

Net Loss Per Common Share

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and should the Company realize net income during the period presented. The cumulative amounts of potentially dilutive securities excluded from the calculation were 13,126,038 securities and 11,103,701 securities for the nine months ended September 30, 2021 and 2020, 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:

	Nine Months Ended September 30,	
	2021	2020
Unvested restricted stock	10,492,731	8,409,696
Options	2,467,537	2,529,133
Warrants	147,058	147,058
Shares issuable upon note conversion	18,712	17,814
Total	13,126,038	11,103,701

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued ASU No 2019-12, Income Taxes (Topic 740): Simplifying Accounting for Income Taxes (ASU 2019-12). ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocations, calculating income taxes in interim periods, and adds certain guidance to remove complexity in certain areas. ASU 2019-12 is effective for all entities for annual and interim periods beginning after December 15, 2020. Early adoption of either the entire standard or only those provisions that eliminate or modify requirements is permitted. Adoption of ASU 2019-12 did not have any impact to our condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, Simplifying the Test for Goodwill Impairment (ASU 2017-04). ASU 2017-04 eliminates the requirement to calculate the implied fair value of goodwill (i.e., Step 2 of today's goodwill impairment test) to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value (i.e., measure the charge based on today's Step 1). The standard has tiered effective dates, starting in 2020 for calendar-year public business entities PBEs that meet the definition of an SEC filer, excluding smaller reporting companies. Early adoption is permitted for annual and interim goodwill impairment testing dates after 1 January 2017. Adoption of ASU 2017-04 did not have any impact to our condensed consolidated financial statements.

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

NOTE 2 REVENUE RECOGNITION

Gross-to-Net Sales Adjustments

To date, our only source of product revenue has been from the U.S. sales of UKONIQ, which we began shipping to our customers in February 2021. We record our best estimate of sales discounts and allowances to which customers are likely to be entitled. The reconciliation of gross product sales to net product sales by each significant category of gross-to-net adjustments was as follows for the three and nine months ended September 30, 2021:

(in thousands)

	Three months ended September 30, 2021	Nine months ended September 30, 2021
Gross product revenue	$ 2,528	$ 5,167
Gross-to-net adjustments:		
Chargebacks and administrative fees	(292)	(487)
Trade discounts and allowances	(128)	(222)
Government rebates and co-payment assistance	(103)	(179)
Sales returns and allowances	(13)	(25)
Total gross-to-net adjustments[(1)]	$ (536)	$ (913)
Net product revenue	$ 1,992	$ 4,254

[(1)] As of September 30, 2021 approximately $0.4 million of estimated gross-net-accruals have been recorded as a reduction of accounts receivable, net and within accounts payable and accrued expenses on the condensed consolidated balance sheets.

NOTE 3 INVESTMENT SECURITIES

Our investments as of September 30, 2021 and December 31, 2020 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following table summarize our investment securities at September 30, 2021 and December 31, 2020:

(in thousands)	September 30, 2021 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 2021 and April 2022) (held-to-maturity)	$ 30,338	$ 3	$ 1	$ 30,340
Long-term investments:				
Obligations of domestic governmental agencies (maturing between February 2023 and June 2023) (held-to-maturity)	24,550	1	12	24,539
Total short-term and long-term investment securities	$ 54,888	$ 4	$ 13	$ 54,879

	December 31, 2020 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 2021 and December 2021) (held-to-maturity)	$ 51,987	$ 1	$ 4	$ 51,984
Total short-term investment securities	$ 51,987	$ 1	$ 4	$ 51,984

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, 2021 and December 31, 2020, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable, approximate their carrying values.

The following tables provide the fair value measurements of applicable financial liabilities as of September 30, 2021 and December 31, 2020:

(in thousands)	Financial liabilities at fair value as of September 30, 2021 Level 1	Level 2	Level 3	Total
5% Notes	$ —	$ —	$ 623	$ 623
Total	$ —	$ —	$ 623	$ 623

	Financial liabilities at fair value as of December 31, 2020 Level 1	Level 2	Level 3	Total
5% Notes	$ —	$ —	$ 938	$ 938
Total	$ —	$ —	$ 938	$ 938

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, 2021:

(in thousands)	
Balance at December 31, 2020	938
Interest accrued on face value of 5% Notes	764
Change in fair value of Level 3 liabilities	(1,079)
Balance at September 30, 2021	$ 623

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 175,000,000 shares of $0.001 par value common stock.

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

We had no activity on the 2021 ATM during the nine months ended September 30, 2021.

The 2019 WKSI Shelf is currently our only active shelf-registration statement. We may offer any combination of the securities registered under the 2019 WKSI Shelf from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that the 2019 WKSI Shelf 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 (the 2012 Incentive Plan) was approved by stockholders in June 2020. As of September 30, 2021, 11,992,744 shares of restricted stock and 2,467,537 options were outstanding and up to an additional 1,746,700 shares may be issued under the 2012 Incentive Plan.

Stock-based compensation expense included in the condensed consolidated statements of operations was $14.0 million and $28.3 million for the three months ended September 30, 2021 and 2020, respectively, and $46.9 million and $46.8 million for the nine months ended September 30, 2021 and 2020, respectively.

The following table summarizes the activity for stock options and restricted stock for the nine months ended September 30, 2021:

(in thousands)	Stock Options	Restricted Stock
Equity awards outstanding, beginning of year	2,526	10,785
Changes during the year:		
Granted	—	2,464
Exercised or vested	(53)	(1,106)
Expired or Forfeited	(6)	(150)
Equity awards outstanding, end of period	2,467	11,993

As of September 30, 2021, total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized were as follows:

(in thousands)	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 523	$ 66,962
Expected weighted-average period in years of compensation cost to be recognized	1.0	1.0

Warrants

The Company's only outstanding warrant is the warrant issued to Hercules as part of our debt agreement to purchase 147,058 shares of common stock with an exercise price of $4.08. See Note 6 for further details. As the warrants could not require cash settlement, the warrants were classified as equity. There will not be any ongoing stock compensation expense volatility associated with these warrants.

NOTE 6 LOAN PAYABLE

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

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%. As a result of the Company having raised in excess of $150 million before the required timeline in the Loan Agreement, the interest-only period was extended to April 1, 2021. At our option, we 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) and all accrued and unpaid interest, subject to a prepayment charges 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 the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and 0% thereafter. In addition, a final payment equal to 3.5% of the aggregate principal amount of the loan extended by Hercules is due on the maturity date. As of September 30, 2021, we have paid approximately $14.6 million of the principal loan balance due to Hercules. The Term Loan repayment schedule continues with monthly principal payments ranging from approximately $2.5 million to $2.7 million per month through March 1, 2022.

The Term Loan is secured by a lien on substantially all of our assets, other than intellectual property, and contains customary covenants and representations. As of September 30, 2021 and through the filing date of this report, the Company has been in compliance with all covenants.

The Loan Agreement contains several events of default, which we are in compliance with all terms. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement. Amounts outstanding during an event of default shall be payable on demand and accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding.

The Loan Agreement also contains warrant coverage of 2% of the total amount funded. A warrant (the Hercules Warrant) was issued to Hercules to purchase 147,058 shares of common stock with an exercise price of $4.08. We accounted for the Hercules Warrant as an equity instrument since it was indexed to our common shares and met the criteria for classification in shareholders' (deficit) equity. The relative fair value of the Hercules Warrant on the date of issuance was approximately $1.0 million and was treated as debt issuance costs and 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 (including the fair value of the Hercules Warrant) related to the Hercules Loan Agreement which are recorded as debt issuance costs and as an offset to loan payable on the Company's unaudited 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 $0.3 million and $0.2 million for each of the three months ended September 30, 2021 and 2020, respectively, and $0.7 million for each of the nine months ended September 30, 2021 and 2020, respectively. At September 30, 2021, the remaining unamortized balance of debt issuance costs was $0.4 million.

The loan payable as of September 30, 2021 and December 31, 2020 is as follows:

(in thousands)	September 30, 2021	December 31, 2020
Loan payable	$ 30,000	$ 30,000
End of term fee	975	975
	30,975	30,975
Less: unamortized debt issuance costs	(386)	(1,080)
	30,589	29,895
Less: principal payments	(14,590)	—
Total loan payable	15,999	29,895
Less: current portion	(15,999)	(22,179)
Loan payable non-current	$ —	$ 7,716

NOTE 7 LEASES

In October 2014, we entered into an agreement (the Office Agreement) with Fortress Biotech, Inc. (FBIO) to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of $1.4 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. At January 1, 2019, we recognized a lease liability and corresponding Right-of-Use (ROU) asset of $9.5 million and $8.1 million, respectively, based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. The present values of our lease liability and corresponding ROU asset are $11.5 million and $8.8 million, respectively, as of September 30, 2021. Our leases have remaining lease terms of 2 years to 10 years. One lease has a renewal option to extend the lease for an additional term of two years.

The initial commitment period of the 45% rate was 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. As of September 30, 2021, the allocation rate is 65% and will be evaluated again in November 2021 for the following rent year. Also in connection with this lease, we have pledged $1.2 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying condensed consolidated balance sheets.

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 took possession of this space in October 2019, with rental payments beginning in November 2019. We incurred rent expense of $0.2 million for the nine months ended September 30, 2021.

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, 2021 and 2020:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 532	$ 534	$ 1,595	$ 1,611
Net lease cost	$ 532	$ 534	$ 1,595	$ 1,611

As of September 30, 2021, the weighted-average remaining operating lease term was 7.4 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, 2021 was $1.5 million.

The balance sheet classification of lease liabilities was as follows:

(in thousands)	September 30, 2021	December 31, 2020
Liabilities		
Lease liability current portion	$ 1,468	$ 1,669
Lease liability non-current	10,020	10,412
Total lease liability	$ 11,488	$ 12,081

As of September 30, 2021, the maturities of lease liabilities were as follows:

(in thousands)	Operating leases
Remainder of 2021	$ 505
2022	2,035
2023	2,040
2024	1,924
2025	1,653
After 2026	9,889
Total lease payments	18,046
Less: interest	(6,558)
Present value of lease liabilities(*)	$ 11,488

(*) 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 8 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, 2021 and 2020, and approximately $114,000 for each of the nine months ended September 30, 2021 and 2020, and at September 30, 2021 and December 31, 2020, have deferred revenue of approximately $0.6 million and $0.8 million, respectively, associated with this $2.0 million payment (approximately $0.2 million of which has been classified in current liabilities at September 30, 2021 and December 31, 2020).

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

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, all wholly owned subsidiaries of LFB Group, relating to the development and commercialization of ublituximab. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. As of September 30, 2021 we have incurred and paid approximately $10.0 million related to milestones. LFB Group is eligible to receive payments of up to an aggregate of approximately $31.0 million upon our successful achievement of certain clinical development, regulatory, and sales milestones, in addition to royalty payments on net sales of ublituximab at a royalty rate that escalates from mid-single digits to high-single digits. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party.

TGR-1202 (Umbralisib)

In September 2014, we exercised our option to license the global rights to umbralisib, thereby entering into an exclusive licensing agreement (the Umbralisib License) with Rhizen Pharmaceuticals, SA (Rhizen) for the development and commercialization of umbralisib. Prior to this, we had been jointly developing umbralisib in a 50:50 joint venture with Rhizen.

During the nine months ended September 30, 2021, we paid Rhizen $12.0 million as part of a primary indication approval milestone for launch of product in the US in accordance with the terms of the Umbralisib License. Rhizen will be eligible to receive additional approval and sales-based milestone payments in the aggregate of approximately $175 million payable upon approval in multiple jurisdictions for up to two oncology indications and one non-oncology indication and attaining certain sales milestones. In addition, if umbralisib is co-formulated with another drug to create a new product (a New Product), Rhizen will be eligible to receive similar regulatory approval and sales-based milestone payments for such New Product. Additionally, Rhizen receives tiered royalties that escalate from high single digits to low double digits on any net sales of umbralisib and any New Product. During the three and nine months ended September 30, 2021, the Company recorded $0.1 million and $0.3 million, respectively, related to the worldwide royalty due under the Umbralisib License in cost of product revenue based on U.S. sales of UKONIQ and as of September 30, 2021, $0.1 million in royalties were payable under the Umbralisib License. Rhizen will also be eligible to participate in sublicensing revenue, if any, based on a percentage that decreases as a function of the number of patients treated in clinical trials following the exercise of the license option. Rhizen will retain global manufacturing rights to umbralisib, provided that they are price competitive with alternative manufacturers. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or any other exclusivity right in such country, unless the agreement is earlier terminated (i) by us for any reason, or (ii) by either party due to a breach of the agreement.

TG-1501: PDL1 (Cosibelimab)

In March 2015, we entered into a Global Collaboration Agreement (Collaboration Agreement) with Checkpoint Therapeutics, Inc. (Checkpoint) for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. The Collaboration Agreement was amended in June 2019 and in March of 2020 we achieved the first milestone event for which we incurred expenses of zero for each of the three months ended September 30, 2021 and 2020, and zero and approximately $0.9 million for the nine months ended September 30, 2021 and 2020, respectively.

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 Brutons Tyrosine Kinase inhibitors containing the compounds of either TG1701 (SHR1459 or EBI1459) or TG-1702 (SHR1266 or EBI1266). Pursuant to the agreement, in April 2018, we paid Hengrui 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 July 2019, we paid Hengrui 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. In July 2020, we paid Hengrui $2.0 million as part of a milestone in accordance with the license agreement. Hengrui is eligible to receive milestone payments totaling approximately $350 million upon and subject to the achievement of certain milestones. Various provisions allow for payments in conjunction with the agreement to be made in cash or our common stock, while others limit the form of payment. Royalty payments in the low double digits are due on net sales of licensed products and revenue from sublicenses. We incurred expenses of approximately $4.2 million and $0.3 million for the three months ended September 30, 2021 and 2020, respectively, and $9.0 million and $0.6 million for the nine months ended September 30, 2021 and 2020, respectively, the majority of which relates to manufacturing expenses of BTK. The relevant expenses are recorded in other research and development in the accompanying unaudited condensed consolidated statement of operations.

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. As of September 30, 2021, we have incurred approximately $2.0 million in milestone expense related to patient enrollment. 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 9 RELATED PARTY TRANSACTIONS

In July 2015, we entered into a Shared Services Agreement (the Shared Services Agreement) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately $0.2 million for each of the three months ended September 30, 2021 and 2020, and expenses of approximately $0.6 million for each of the nine months ended September 30, 2021 and 2020, primarily related to shared personnel.

Please refer to Note 7 - Leases for details regarding the Office Agreement with FBIO, as well as Note 8 - License Agreements for details regarding the Collaboration Agreement with Checkpoint.

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. Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the COVID-19 pandemic. 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, 2020.

OVERVIEW

TG Therapeutics is a fully integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines across these therapeutic areas, UKONIQ received accelerated approval from the FDA for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20-based regimen and adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapies. Currently, we have three programs in Phase 3 development for the treatment of patients with RMS and patients with CLL and several investigational medicines in Phase 1 clinical development. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

FDA Accelerated Approval of UKONIQ and Commercial Launch

On February 5, 2021, we announced that the FDA granted accelerated approval of UKONIQ for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20 based regimen and for the treatment of adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapy. UKONIQ is the first and only, oral, once-daily, inhibitor of phosphoinositide 3 kinase (PI3K) delta and casein kinase 1 (CK1) epsilon. Accelerated approval was granted for these indications based on overall response rate (ORR) data from the Phase 2b UNITY-NHL Trial (NCT02793583). Continued approval for these indications is contingent upon verification and description of clinical benefit in a confirmatory trial. UKONIQ was granted orphan drug designations (ODD) for the treatment of MZL and FL.

Following the FDA approval, we launched UKONIQ, making it available to patients through a distribution network that includes a specialty pharmacy and specialty distributors. Payor coverage of UKONIQ and inclusion in the NCCN guidelines have been consistent with the FDA-approved indications. We are committed to helping patients access their prescription for UKONIQ through the TG Patient Support Program, which we launched following the approval of UKONIQ.

Our Products Under Development

We have leveraged our B-cell platform to develop a robust drug pipeline of small molecule kinase inhibitors and intravenously delivered immunotherapies that leverage the patients' own immune system. The following table summarizes our most advanced drug candidates:

Clinical Drug Candidate: (molecular target)	**Initial Target Disease**	**Stage of Development (trial name)**
Ublituximab (anti-CD20 mAb) and UKONIQ (PI3K-delta and CK1-epsilon inhibitor)	Chronic Lymphocytic Leukemia (CLL) and Relapsed or Refractory Marginal Zone Lymphoma (MZL)	Phase 3 trial (UNITY-CLL) Phase 3 trial (ULTRA-V) Phase 2b trial (UNITY-NHL)
Ublituximab (anti-CD20 mAb)	Relapsing Forms of Multiple Sclerosis (RMS)	Phase 3 trials (ULTIMATE I and II)
Cosibelimab/TG-1501 (anti-PDL1 mAb)	B-cell cancers	Phase 1 trial
TG-1701 (BTK inhibitor)	B-cell cancers	Phase 1 trial
TG-1801 (anti-CD47/CD19 bispecific mAb)	B-cell cancers	Phase 1 trial

Phase 2b and Phase 3 Clinical Trial Updates

The following are updates from our current Phase 2b and Phase 3 clinical trials:

UNITY-NHL Phase 2b Trial: UNITY-NHL is a broad, multicenter, open-label, Phase 2b registration-directed clinical trial designed to evaluate the efficacy and safety of UKONIQ monotherapy and UKONIQ plus ublituximab (U2) combinations in patients with previously treated NHL. There are several exploratory cohorts of the UNITY-NHL trial which are enrolled to and evaluated independently from the others, including cohorts for MZL, FL/SLL, DLBCL, and MCL.

- On November 4, 2021, TG abstracts to be presented during the American Society of Hematology (ASH) 2021 annual meeting were made publicly available, which included updates from U2 cohort in patients with relapsed or refractory MZL and an update from the U2 plus bendamustine cohort in relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL).

UNITY-CLL Phase 3 Trial Evaluating UKONIQ plus Ublituximab (U2): UNITY-CLL is a global, multi-center, 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 UKONIQ were also enrolled for purposes of evaluating the contribution of each drug in the U2 combination regimen. The primary endpoint for this study was progression-free survival (PFS). The study completed enrollment in October 2017 with over 600 patients across the four treatment arms, with approximately 420 patients enrolled in the U2 and the active control arms combined. This trial was conducted under a Special Protocol Assessment (SPA) with the FDA. The UNITY-CLL trial was led by John Gribben, MD, Professor of Medical Oncology, Barts Cancer Institute, United Kingdom.

- On December 7, 2020, we presented safety and efficacy results from the UNITY-CLL trial at the ASH Annual meeting demonstrating that U2 significantly improved PFS over obinutuzumab plus chlorambucil (HR=0.54, $p<0.0001$) as well as ORR ($p<0.001$) in patients with CLL, with consistent PFS improvement across treatment naïve CLL (HR=0.48) and relapsed or refractory CLL (HR=0.60). Grade 3/4 adverse events (AEs) of clinical interest (U2 vs Obin+Chl) included elevated ALT (8.3% vs 1.0%), elevated AST (5.3% vs 2.0%), non-infectious colitis (1.9% vs 0%), infectious colitis (0.5% vs 0.5%), pneumonitis (0.5% vs 0%), rash (2.4% vs 0.5%), and opportunistic infections (5.8% vs. 1.5%).

- Based on data from the UNITY-CLL Phase 3 trial, submissions of a Biologics License Application (BLA) and a supplemental New Drug Application (sNDA) were made for ublituximab, in combination with UKONIQ, as a treatment for patients with CLL and small lymphocytic lymphoma (SLL). The BLA and sNDA have been accepted by the FDA and a Prescription Drug User Fee Act (PDUFA) goal date of March 25, 2022 has been set for both applications.

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 the efficacy and safety/tolerability of ublituximab (450mg dose administered by one-hour intravenous infusion every 6 months, following a Day 1 infusion of 150mg over four hours and a Day 15 infusion of 450mg over one hour) versus teriflunomide (14mg oral tablets taken once daily) in subjects with RMS. These trials were conducted under a SPA with the FDA. The ULTIMATE I and II trials were led by Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University. Full enrollment was completed in October 2018, with approximately 1,100 subjects enrolled in both studies combined.

- In April 2021, data from the ULTIMATE I and II trials were presented at the American Academy of Neurology Annual meeting. Both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period ($p<0.005$ in each trial). Key secondary MRI endpoints were also met.

- In September 2021, a BLA was submitted to the FDA for ublituximab to treat patients with RMS, based on data from the ULTIMATE I and II Phase 3 trials.

ULTRA-V Phase 2/3 Trial Evaluating U2 Plus Venetoclax in CLL: The ULTRA-V Study is being conducted in two parts. The initial Phase 2 portion completed enrollment in 1Q21. The Phase 3 portion commenced at approximately the same time. The ULTRA-V trial is designed to investigate the efficacy and safety of U2 in combination with venetoclax in subjects with treatment-naïve CLL and relapsed or refractory CLL. The ULTRA-V Phase 2 trial is being led by Dr. Richard R. Furman, Morton Coleman, MD Distinguished Professor of Medicine Weill Cornell Medical College.

- The ULTRA-V Phase 2 portion of the trial is an open-label, multi-center, clinical trial, and the primary endpoints for this study are ORR and Complete Response (CR) rate. This trial completed enrollment with approximately 165 patients.

- The ULTRA-V Phase 3 portion of the trial is an open-label, multi-center, randomized, controlled clinical trial comparing the time-limited triple combination of U2 plus venetoclax to an active control arm of continuous U2. The Phase 3 trial includes two independent randomized cohorts of CLL subjects: a treatment-naïve cohort and a previously treated cohort, with each cohort being enrolled and evaluated independently of each other. The primary endpoint for the trial is PFS.

RESULTS OF OPERATIONS

Three months ended September 30, 2021 and 2020

Product Revenues (Net). Net product revenues represent U.S. sales from our sole commercial product, UKONIQ, which was approved by the FDA on February 5, 2021. During the three months ended September 30, 2021, net product revenues were $2.0 million. Sales allowances and accruals consisted of government rebates, patient financial assistance, distribution fees, discounts, and chargebacks. We did not have product revenues in 2020.

Cost of Product Revenue. Cost of product revenue for the three months ended September 30, 2021 was $0.3 million. Cost of product revenue primarily relates to freight and royalties owed to our licensing partner for UKONIQ sales. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, the manufacturing costs of UKONIQ units recognized as revenue during the three months ended September 30, 2021 were expensed prior to the February 5, 2021 FDA approval, and therefore are not included in costs of product revenue during the current period. We expect the cost of product revenue to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the second quarter of 2022.

License Revenue. 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. License revenue was approximately $38,000 for each of the three months ended September 30, 2021 and 2020 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 $4.5 million for the three months ended September 30, 2021, as compared to $4.6 million during the comparable period in 2020. The decrease in noncash compensation expense was primarily due to vesting of milestone-based grants in the prior period.

Other Research and Development Expenses. Our other 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.

Other research and development expenses increased by $1.6 million to $47.4 million for the three months ended September 30, 2021, as compared to $45.8 million for the three months ended September 30, 2020. The increase in R&D expense is primarily attributable to increased headcount and ongoing late-stage clinical development programs, offset by a decrease in license milestones..

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants decreased by $14.2 million to $9.5 million for the three months ended September 30, 2021, as compared to $23.7 million for the three months ended September 30, 2020. The decrease in noncash compensation expense was primarily related to greater compensation expense during the three months ended September 30, 2020 related to restricted stock and stock options granted to executive personnel.

Other Selling, General and Administrative Expenses. Our selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, commercial, medical, and other administrative personnel, recruitment expenses, expenses for commercialization activities (including the build out of our medical affairs and commercial organizations and infrastructure), professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

Other selling, general and administrative expenses was $25.4 million for the three months ended September 30, 2021, as compared to $11.6 million for the three months ended September 30, 2020. The increase was due primarily to increased personnel and other selling, general and administrative costs, associated with execution of the launch of UKONIQ and planning for the potential launches of U2 in CLL and ublituximab in RMS. We expect our selling, general and administrative expenses to increase for the remainder of 2021 as we continue to prepare for those potential 2022 launches.

Interest Expense. Interest expense decreased by $0.6 million to $1.0 million for the three months ended September 30, 2021, as compared to $1.6 million for the three months ended September 30, 2020. The decrease is mainly due to greater interest expense related to administrative fees in connection with contract manufacturing costs during the three months ended September 30, 2020.

Other Income. Other income was $0.5 million for the three months ended September 30, 2021, as compared to $0.2 million for the three months ended September 30, 2020. The increase is mainly due to greater interest income and an increase in the change in fair value of notes payable for the three months ended September 30, 2021. We expect our other income to remain at a comparable level for the remainder of 2021.

Nine months ended September 30, 2021 and 2020

Product Revenues (Net). Net product revenues represent U.S. sales from our sole commercial product, UKONIQ, which was approved by the FDA on February 5, 2021. During the nine months ended September 30, 2021, net product revenues were $4.3 million. Sales allowances and accruals consisted of government rebates, patient financial assistance, distribution fees, discounts, and chargebacks. We did not have product revenues in 2020.

Cost of Product Revenue. Cost of product revenue for the nine months ended September 30, 2021 was $0.6 million. Cost of product revenue primarily relates to freight and royalties owed to our licensing partner for UKONIQ sales. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, the manufacturing costs of UKONIQ units recognized as revenue during the nine months ended September 30, 2021 were expensed prior to the February 5, 2021 FDA approval, and therefore are not included in costs of product revenue during the current period. We expect the cost of product revenue to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the second quarter of 2022.

License Revenue. 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. License revenue was approximately $114,000 for each of the nine months ended September 30, 2021 and 2020 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 $19.1 million for the nine months ended September 30, 2021, as compared to $8.1 million during the comparable period in 2020. The increase in noncash compensation expense was primarily due to vesting of milestone-based grants, an increase in research and development personnel and the vesting of grants with a higher stock price during the nine months ended September 30, 2021, as compared to previous periods.

Other Research and Development Expenses. Our other 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.

Other research and development expenses increased by $26.1 million to $140.9 million for the nine months ended September 30, 2021, as compared to $114.8 million for the nine months ended September 30, 2020. The increase in R&D expense is primarily attributable to consulting fees associated with the submission of our BLA for ublituximab in RMS, the achievement of license milestones, and increased manufacturing costs during the nine months ended September 30, 2021.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants decreased by $10.8 million to $27.9 million for the nine months ended September 30, 2021, as compared to $38.6 million for the nine months ended September 30, 2020. The decrease in noncash compensation expense was primarily related to greater compensation expense during the nine months ended September 30, 2020 related to restricted stock and stock options granted to executive personnel.

Other Selling, General and Administrative Expenses. Our selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, commercial, medical, and other administrative personnel, recruitment expenses, expenses for commercialization activities (including the build out of our medical affairs and commercial organizations and infrastructure), professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

Other selling, general and administrative expenses was $67.8 million for the nine months ended September 30, 2021, as compared to $25.4 million for the nine months ended September 30, 2020. The increase was due primarily to increased personnel and other selling, general and administrative costs associated with execution of the launch of UKONIQ and planning for the potential launches of U2 in CLL and ublituximab in RMS. We expect our selling, general and administrative expenses to increase for the remainder of 2021 as we continue to prepare for those potential 2022 launches.

Interest Expense. Interest expense remained relatively consistent at $4.6 million for the nine months ended September 30, 2021, as compared to $5.0 million for the nine months ended September 30, 2020.

Other Income. Other income was $1.6 million for the nine months ended September 30, 2021, as compared to $0.7 million for the nine months ended September 30, 2020. The increase is mainly due to greater interest income and an increase in the change in fair value of notes payable for the nine months ended September 30, 2021. We expect our other income to remain at a comparable level for the remainder of 2021.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from the private placement and public offering of equity securities. In February of 2021, umbralisib, now referred to as UKONIQ, was granted accelerated approval in the United States for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapy. Commercial sales of UKONIQ commenced in the first quarter of 2021. We have generated limited revenues to date from product sales. Even with the commercialization of UKONIQ and the potential future commercialization of our other drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to generate revenue, our ability to obtain regulatory approvals for our drug candidates, our ability to successfully complete any post-approval regulatory obligations and our ability to successfully commercialize our drug candidates. We may continue to incur substantial operating losses even as we begin to generate revenues from product sales.

As of September 30, 2021, we had $381.4 million in cash and cash equivalents, and investment securities. We anticipate that our cash and cash equivalents, and investment securities as of September 30, 2021 will provide sufficient liquidity for more than a twelve-month period from the date of filing this Quarterly Report on Form 10Q. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, our UKONIQ commercialization efforts, preparations for the commercialization of our other drug candidates, and 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 ongoing and future operations, including the commercialization of any additional drug candidates. In addition, we may in-license additional compounds that may require upfront fees and milestone payments.

Discussion of Cash Flows

Cash used in operating activities for the nine months ended September 30, 2021 was $208.7 million as compared to $162.5 million for the nine months ended September 30, 2020. The increase in cash used in operating activities was due primarily to increased expenditures associated with execution of the launch of UKONIQ, our scale-up for manufacturing, ongoing clinical development programs and paydown of accounts payable and accrued expenses.

Net cash used in investing activities for the nine months ended September 30, 2021, was $3.6 million as compared to cash provided by investing activities of $27.6 million for the nine months ended September 30, 2020. The increase in net cash used in investing activities was primarily due to greater investment in short-term and long-term securities during the nine months ended September 30, 2021.

Net cash used in financing activities for the nine months ended September 30, 2021, was $14.6 million as compared to cash provided by financing activities of $276.4 million for the nine months ended September 30, 2020. The period ended September 30, 2020 included proceeds from the issuance of common stock as part of our underwritten public offering in May 2020 and our ATM program.

ATM Program

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

The 2019 WKSI Shelf is currently our only active shelf-registration statement. We may offer any combination of the securities registered under the 2019 WKSI Shelf from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that the 2019 WKSI Shelf provides us with the flexibility to raise additional capital to finance our operations as needed.

Equity Financings

In May 2020, we completed an underwritten public offering of 8,500,000 shares of our common stock (plus an underwriter option to purchase up to an additional 1,275,000 shares of common stock, which was exercised) at a price of $18 per share. Net proceeds from this offering, including the overallotment, were approximately $165.1 million, net of underwriting discounts and offering expenses of approximately $10.8 million.

On December 17, 2020, we completed a public offering of 6,320,000 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 948,000 shares of common stock, which was exercised) at a price of $43.50 per share. Net proceeds from this offering, including the overallotment, were approximately $297.2 million after underwriting discounts and offering expenses of approximately $19.0 million.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES AND ACCOUNTING ESTIMATES

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For a description of our significant accounting policies, refer to "Part II, Item 8. Financial Statements and Supplementary Data, Note 1 – Organization and Summary of Significant Accounting Policies" in our 2020 Annual Report on Form 10-K, and refer to Note 1 in this Quarterly Report on Form 10-Q for significant accounting policies due to commercialization for revenue recognition, gross-to-net sales adjustments, accounts receivable, inventory, and cost of product revenue. Of these policies, the following are considered critical to an understanding of our Unaudited Condensed Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments: stock-based compensation expenses, and fair value measurement of financial liabilities. Refer to "Note 5 – Stockholders' Equity" and "Note 4 - Fair Value Measurements," respectively, for more information.

RECENTLY ISSUED ACCOUNTING STANDARDS

Refer to "Note 1 - Organization and Summary of Significant Accounting Policies" in the Notes to Unaudited Condensed Consolidated Financial Statements for a discussion of recently issued accounting pronouncements, and their expected impact on our financial position and results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk has not changed materially since our disclosure in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2021, 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, 2021, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2021 that 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 risk factors and the other information contained elsewhere in this Quarterly Report before making an investment in our securities. If any of the following risks occur, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. The risks described below are not the only ones that our business faces. Additional risks not currently known to us or that we currently deem to be immaterial may adversely impact our business in the future. Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the COVID-19 pandemic.

Risks Related to Commercialization

If UKONIQ, or any product candidate for which we in the future obtain regulatory approval, does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from product sales will be limited.

We have one marketed product, UKONIQ, which received accelerated approval from the FDA on February 5, 2021 for the treatment of relapsed or refractory MZL in adult patients who have received at least one prior anti-CD20-based regimen and relapsed or refractory FL in adult patients who have received at least three prior lines of systemic therapy. In addition, the FDA accepted our BLA and sNDA requesting approval of ublituximab in combination with UKONIQ as a treatment for patients with CLL/SLL and set a Prescription Drug User Fee Act (PDUFA) goal date of March 25, 2022 for the BLA and sNDA, and on September 30, 2021, we announced the submission of a BLA for ublituximab for the treatment of relapsing forms of multiple sclerosis (RMS).

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

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

The COVID-19 pandemic continues to present a substantial global public health and economic challenge. The measures to control the virus's spread have impacted our approach to the commercial launch of UKONIQ and may impact our ability to successfully launch ublituximab, if approved. We initiated commercial sales of UKONIQ in February 2021 in an environment in which the measures taken by state and local governments as well as hospitals and oncology clinics to control the spread of COVID-19 significantly limited our opportunities for in-person interactions, including for example, interactions with physicians, hospitals, payors, and other customers at medical congresses. As a result of COVID-19 variants, many of the interactions our field personnel have with healthcare providers and other customers continue to be virtual. We cannot ensure that remote methods will be effective or as effective as in-person interactions. Other factors related to the COVID-19 pandemic that could impact the ongoing launch and potential future launches include delays in demand due to a reduction in medical visits by patients, impacts on the healthcare system and overall economy and increases in the number of uninsured or underinsured patients. In addition, our office-based employees, consultants, vendors and certain customer segments are continuing to work remotely and many of our commercialization efforts are happening virtually. The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts our commercialization efforts depend on future developments that are highly uncertain, subject to change and are difficult to predict, including, whether, even after pandemic-related restrictions ease, there is a shift in how pharmaceutical field representatives interact with healthcare providers that could have a negative effect on our future business and operations. For a discussion of additional pandemic-related risks to our business, see below under the heading "**Risks Related to the COVID-19 Pandemic**".

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

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

Regulatory approvals for any of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the approved product candidate.

With respect to the FDA's approval of UKONIQ for relapsed or refractory MZL and FL, we received accelerated approval and are subject to certain post-approval requirements. For example, we will need to conduct a confirmatory clinical trial, which will involve a Phase 3 trial that may be expensive and time-consuming and may not confirm the benefit making the MZL and FL indications for UKONIQ subject to withdrawal of continued approval by the FDA, which could significantly harm our business. In addition, we will need to conduct additional clinical studies to address post-marketing commitments and post-marketing requirements related to further assessing the drug-drug interaction profile of UKONIQ and its safety, efficacy, and pharmacokinetic properties in certain at-risk populations. These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market UKONIQ, or negatively impact its overall clinical profile.

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

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

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

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

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

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

The precise incidence and/or prevalence of relapsed or refractory MZL after one prior anti-CD20-based regimen, relapsed or refractory FL after three prior lines of systemic therapy, CLL, and relapsing forms of MS are unknown. Our projections of both the number of patients within our FDA-approved indications for UKONIQ and target indications for U2 in CLL/SLL and ublituximab in MS, as well as the subset of these patients who have the potential to benefit from treatment with our products, are based on estimates. These estimates are typically based on one on one and group interactions with target physicians and other sources available at the time we make the estimates, including the scientific literature, healthcare utilization databases and market research. Although we believe our estimates are reasonable, many factors may limit their accuracy. For example, the sources we use to make the estimates may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases and the number of patients may turn out to be lower than expected.

The total addressable market opportunity for UKONIQ in MZL and FL, U2 in CLL/SLL, and ublituximab in MS will ultimately depend upon, among other things, the scope of the final approved indication and other elements of the approved prescribing information, acceptance by the medical community, patient access, and drug pricing and reimbursement. The number of patients in major markets, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, new patients may become increasingly difficult to identify or gain access to, 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, which may result in others commercializing drugs before or more successfully than we do resulting in the reduction or elimination of our commercial opportunity.

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and commercialization resources. Large pharmaceutical companies have extensive experience 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 more effective, have fewer or less severe side effects, are more convenient or are priced or contracted differently than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. In a competitive environment, a company’s communications may also be subject to heightened scrutiny from regulators and competitors, under laws, regulations, and guidance about promotional communications (advertising and promotional labeling) and non-promotional communications (e.g., certain educational and scientific exchange); and with regard to potential competitor actions under federal law (the Lanham Act) and congruous state law, which protect businesses against the unfair competition of misleading advertising or labeling.

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

For the cancer indications for which we received FDA approval of UKONIQ or for which we are developing our product candidates, there are a number of established therapies with which we will compete:

- For the treatment of MZL, we expect UKONIQ to compete with zanubrutinib (BeiGene), ibrutinib (AbbVie and Janssen), and the combination of rituximab and lenalidomide (Bristol-Myers Squibb), as well as established treatments such as rituximab (Roche) and several generically available chemotherapies. In addition, there are investigational PI3K inhibitors being developed in MZL.
- For the treatment of FL, we expect UKONIQ to compete with recently approved drugs such as axicabtagene ciloleucel (Gilead), obinutuzumab (Roche), idelalisib (Gilead), copanlisib (Bayer), duvelisib (Verastem), tazemetostat (Epizyme), and the combination of rituximab and lenalidomide (Bristol-Myers Squibb), and established treatments such as rituximab (Roche), and several generically available chemotherapies, many of which have FDA-approved indications for earlier lines of therapy (e.g., after two prior lines of systemic therapy) than UKONIQ. There are also several PI3K delta inhibitors in earlier stages of development for FL.
- For the treatment of CLL, if U2 is approved, we expect the regimen to compete with recently approved drugs such as ibrutinib (AbbVie and Janssen), acalabrutinib (AstraZeneca), 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 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. These agents can be used as monotherapy or in combination with one or more of the other agents.
- 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 UKONIQ.

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 are two anti-CD20 monoclonal antibodies approved, ocrelizumab (Roche) and ofatumumab (Novartis).

Cosibelimab, TG-1701 and TG-1801 if approved will also face competition from drugs on the market and under development in the same therapeutic class 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.

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

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. 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 product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products, even if our product candidates obtain marketing approval. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. In addition, if we are successful in obtaining FDA approval for ublituximab for the treatment of CLL/SLL and MS, we will need to identify and execute a pricing strategy that takes into account the value of the product in each indication independently to realize the product's full potential in both indications. If we are unable to identify and execute such a strategy, the pricing of ublituximab across indications may not be optimal, which may have a material adverse impact on the sales in one or both of the indications and on our overall business.

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

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

If, in the future, we are unable to expand our commercial operation, including 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 product candidates if and when they are approved, and we may not be able to generate any revenue.

We have made and continue to make significant investments in our commercial organization and infrastructure. We have hired and continue to hire marketing, sales, and medical support personnel and have built processes and systems to support the commercialization of UKONIQ in the U.S. We are expanding our commercialization team and infrastructure in planning for the potential commercial launches of U2 in CLL/SLL and ublituximab in MS prior to knowing whether the FDA will accept or approve the necessary regulatory submissions. It is possible that either or both FDA approvals are unexpectedly delayed or are not received 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 establishing our own sales, marketing, and other commercialization capabilities. For example, recruiting and training a sales force are expensive and time-consuming and could delay any drug launch. If the commercial launch of a product candidate (e.g., U2 in CLL/SLL or ublituximab in MS) 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 UKONIQ and our product candidates on our own and generate product revenues include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on the applicable disease states, products, competitors, and legal and regulatory compliance matters;
- the inability of sales personnel to obtain access to physicians or to effectively promote UKONIQ or 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;
- our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

In the future, we may choose to participate in sales activities with collaborators for some of our product candidates if and when they are approved. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

We are also planning for expansion into certain European markets. Building and maintaining an infrastructure outside the United States is expensive, complex, resource intensive and time consuming. Like the situation described above in the U.S., we will need to establish our infrastructure in planning for the potential commercial launches in Europe prior to knowing whether the regulatory authorities will accept or approve the regulatory submissions or approve any of our products at an appropriate price. In either case we will incur delays that may impede or significantly delay our ability to generate revenue in those international markets and at the same time will incur significant expenses. If this were to occur, it would have a material adverse effect on the Company.

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

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

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

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

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

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, undertaking pre-clinical studies and clinical trials, commercializing our only marketed product UKONIQ, which received FDA approval in February 2021, and preparing for potential commercialization of ublituximab. We are transitioning 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 our efforts and financial resources on clinical trials, manufacturing of our drug candidates, and preparing to support a commercial product. To date, we have financed our operations primarily through public offerings of our common stock and a debt financing. Since inception, we have incurred significant operating losses. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. Other than the FDA approval of UKONIQ, we have not obtained marketing approval for any of our product candidates, which are in preclinical or clinical development stages. We expect to continue to incur significant research and development expenses in connection with continuing our existing clinical trials and beginning additional clinical trials. In addition, we expect to continue to incur significant sales, marketing and outsourced-manufacturing expenses as we commercialize UKONIQ and plan for the possible commercialization of ublituximab in CLL/SLL and RMS, if approved. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

To date, we have not generated any significant revenue from our product sales, and it is uncertain when and if we will generate any significant revenue from the sale of our products in the future. Furthermore, no assurance can be given that we will meet revenue projections or guidance. To obtain significant and sustained revenues and meet our revenue projections or guidance, we must succeed, either alone or with others, in (i) developing and obtaining regulatory approval for our product candidates, including ublituximab, and for additional indications of UKONIQ; and (ii) manufacturing and marketing our products and product candidates. Accordingly, we do not expect to generate significant and sustained revenue unless and until we obtain marketing approval of ublituximab and additional indications of UKONIQ and/or one of our other product candidates. Our ability to generate significant and sustained revenue or meet revenue projections or guidance depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety, pharmacokinetic, biodistribution, and non-clinical studies required to obtain U.S. and foreign marketing approval for our product candidates;
- obtain approval from the FDA and foreign equivalents to market and sell our product candidates, including ublituximab in CLL /SLL and RMS, and maintain FDA approval of UKONIQ for relapsed or refractory MZL and FL;
- establish commercial manufacturing capabilities with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our product candidates, or, in the case of UKONIQ, maintain these capabilities;
- expand on our commercial infrastructure to commercialize ublituximab, our other product candidates, and additional indications of UKONIQ, if approved, by increasing the size of our sales force and commercialization infrastructure and/or entering into collaborations with third parties; and
- achieve market acceptance of UKONIQ and our product candidates, if approved, in the medical community and with third-party payors.

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

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, ublituximab, cosibelimab, TG-1701 and TG-1801, and UKONIQ for additional indications 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, seek marketing approval for, and expand our infrastructure to commercialize our product candidates and additional indications of UKONIQ. Moreover, in anticipation of potential regulatory approvals for UKONIQ and ublituximab in CLL/SLL and for ublituximab in RMS, we will need to expend substantial resources on manufacturing and BLA support over the next 12 to 18 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;
- developments relating to the COVID-19 pandemic in the U.S. and around the world;
- the costs and timing of regulatory approvals;
- the costs and timing of clinical and commercial manufacturing supply arrangements for each product and product candidate;
- the costs of expanding our sales, distribution, and other commercialization capabilities;
- the success of the commercialization of UKONIQ and any product candidates, if approved;
- 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 studies 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 successful commercialization of UKONIQ, ublituximab (if approved), or any of our other product candidates and otherwise forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect to stockholders. Currently, other than UKONIQ, our products are investigational and have not been approved by the FDA or any foreign regulatory authority for sale. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from sales of UKONIQ in the U.S., cash on hand and amounts raised in future offerings or financings. Accordingly, our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of commercial operations and the competitive environment in which we operate.

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

Until such time, if ever, as we can generate substantial 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 6 to our consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or 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 commercialization and 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 our commercialization efforts and the development of our product candidates. In the event we do not successfully raise subsequent financing, our commercialization and product development activities will necessarily be curtailed commensurate with the magnitude of the shortfall. If our commercialization or 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 commercialization activities or the development of 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.

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 6 to our 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. As of September 30, 2021, we had outstanding obligations of $16.0 million under the Loan Agreement. In addition, we have short-term liabilities of approximately $10.9 million with a contract manufacturing organization (CMO) for the scale-up, tech-transfer, and long-term supply of one of our drug candidates. To date, this CMO has provided payment terms which we believe are reasonable. No assurance can be given that such terms will continue to be available to us in the future.

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 ourselves. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the Term Loan for its benefit, which collateral includes substantially all 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 product candidates and ultimately cannot commercialize one or more of them, or experience significant delays in doing so, our business will be materially harmed.

We have invested substantially all of our efforts and financial resources in the identification and pre-clinical and clinical development of UKONIQ and our product candidates, including ublituximab, cosibelimab, TG-1701 and TG-1801, and building a commercial infrastructure. Our ability to generate revenues from product sales will depend completely on the successful completion of our current and future Phase 3 and registration-directed clinical trials and commercialization of our product candidates and additional indications of UKONIQ, which may never occur. Each of our product candidates will require additional non-clinical or clinical development, regulatory approval in multiple jurisdictions, and we will need to obtain sufficient clinical and commercial supply. The success of our development programs and achievement of regulatory approval of our product candidates will depend on several factors, including the following:

- successful completion of our clinical programs with positive results that support a finding of effectiveness and an acceptable safety profile of our product candidates in the intended populations within the timeframes we have projected;
- INDs and clinical trial applications, or CTAs, being cleared/approved such that our product candidates can commence clinical trials;
- successful initiation and completion of preclinical studies and successful initiation of, enrollment in and completion of clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for our product candidates, including U2 in CLL and ublituximab in RMS;
- establishing commercially viable arrangements with third-party manufacturers for clinical supply and commercial manufacturing; and
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by the COVID-19 pandemic and related work stoppages across the globe;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs or ECs to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other therapies in the same or a similar class that raise safety or efficacy concerns about our product candidates.

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

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

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. Any delays in our pre-clinical or future clinical development programs may harm our business, financial condition and prospects significantly. We may also incur additional costs if enrollment is increased. 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.

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

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

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 higher than expected and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to 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. In addition, data may emerge, from confirmatory or other post-marketing studies, or from pharmacovigilance reporting, as products are used more widely, or for a longer duration, after approval that may affect the commercial potential of our products. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Many of our ongoing and planned clinical studies involve combinations of two or more drugs. In drug combination clinical development, there is an inherent risk of drug-drug interactions between combination agents that may affect each component's individual pharmacologic properties and the overall efficacy and safety of the combination regimen. Both ublituximab and UKONIQ are being evaluated in combination with each other, as well as with a variety of other active anti-cancer agents, which may cause unforeseen toxicities, 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 cosibelimab, 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.

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, packaging, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, and pharmacovigilance and adverse event reporting of our product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities worldwide. In the United States, we are not permitted to market a product candidate until we receive approval of a BLA or NDA from the FDA. The process of obtaining a BLA or NDA approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition,

approval policies or regulations may change over time. If we fail to gain approval to commercialize our product candidates from the FDA and other foreign regulatory authorities in the timelines we project or at all, we may be unable to generate the revenues that we may project or generate revenues at levels sufficient to sustain our business.

The FDA and foreign regulatory authorities have substantial discretion in the pharmaceutical product approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. During the regulatory review process, the FDA or other regulatory authorities may disagree with or not accept our clinical trial design, may have questions about the potential impact of our study design on conclusions that can be drawn from the data, may interpret results differently than we do, and may change its view on the criteria that must be met for approval. This could happen even for a protocol that has received a SPA. In September 2015, we announced a Phase 3 clinical trial for U2 for patients with CLL, which is being conducted pursuant to a SPA with the FDA (UNITY-CLL). In addition to the SPA for UNITY-CLL, in August 2017 we announced SPAs for the ULTIMATE I and II studies evaluating ublituximab in RMS. There have been examples of companies that have been granted SPAs and have ultimately failed to obtain final approval to market their drugs. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval.

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

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

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is tolerable and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies and/or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other marketing authorization submission to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may 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;
- during the course of review, the FDA or foreign regulatory authorities may raise issues and request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC), or other data and information, and the development and provision of these data and information may be time consuming. We may not be able to generate the data within the time period necessary to obtain approval within the established regulatory review timelines, such as by a PDUFA goal date or at all to satisfy the FDA or foreign regulatory authorities;

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; or
- interruptions or delays in the operations of the FDA and foreign regulatory authorities as a result of the COVID-19 pandemic may negatively impact review, inspection, and approval timelines.

Even if we succeed in obtaining regulatory approval, the FDA may require post-marketing studies, including additional clinical trials such as those necessary to assess drug interactions or activity of a product in specific populations which also may be costly. For example, as part of the accelerated approval of UKONIQ for relapsed or refractory MZL and FL, continued approval for those indications is contingent upon verification and description of clinical benefit in a confirmatory trial. The outcomes of post-marketing studies may also impact product labeling and therefore there can be no guarantee that the product attributes contained in the initial prescribing information will be maintained as future studies produce data. This includes, without limitation, additional results from studies evaluating drug-drug interactions and patients with certain comorbidities (e.g., hepatic or renal impairment or cardiac risks) among others that may restrict the use of an approved product in select populations or introduce dose modifications or contraindicated concomitant medications that have the potential to impact the utility of a product or its perceived product profile among prescribers. Post-marketing studies may also lead to the introduction of new warnings in the product prescribing information. For example, post-marketing studies may lead to the addition of a boxed warning for UKONIQ. The inclusion of a boxed warning or other required warning language or the addition of limitations to the use of the product within the indicated population could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a REMS program requiring prescriber training or a post-marketing registry or may restrict the marketing and dissemination of our products. Any requirements to conduct post-approval studies or fulfill special post-approval requirements could impact our ability to commercialize our product candidates and increase our costs.

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

We may seek Breakthrough Therapy or Fast Track designation for some of our drug candidates. For example, in January 2019, the FDA granted Breakthrough Therapy designation to UKONIQ for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen, and in October 2020, the FDA granted Fast Track designation to the investigation of ublituximab in combination with UKONIQ for the treatment of adult patients with CLL. If a drug is intended for the treatment of a serious or life-threatening condition, and the drug demonstrates the potential to address an unmet medical need for this condition, the Sponsor may apply for Fast Track designation or Breakthrough Therapy designation, the latter of which has more significant requirements. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular drug candidate is eligible for such a designation, we cannot be sure that the FDA would decide to grant it. Even if we receive Breakthrough Therapy or Fast Track designation for a drug candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A drug that receives Fast Track designation is eligible for more frequent interactions with the FDA, priority review if relevant criteria are met, and rolling submission of the BLA or NDA. Even if rolling review is allowed, there is no guarantee that the FDA will have commenced or completed review of the BLA or NDA modules submitted earlier in the rolling review process. Neither Breakthrough Therapy nor Fast Track designation guarantees Priority Review of an NDA or BLA application. Despite receiving Fast Track designation for U2 for the treatment of adult patients with CLL, the FDA granted the BLA a standard review timeline with a PDUFA goal date of March 25, 2022. The FDA may also withdraw a Breakthrough Therapy or Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We have received orphan drug designation for some of our drug candidates for specified indications, and we may seek additional orphan drug designations for other indications 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 as monotherapy 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 2010, and received orphan drug designation by the EMA for the treatment of CLL in November 2009. We also obtained orphan drug designation for umbralisib as monotherapy for the treatment of CLL in August 2016, all three types of MZL (nodal, extranodal and splenic) in April 2019, and FL in March 2020. 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; however, we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States, the European Union, and the United Kingdom, may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Orphan drug designations are required to be maintained through annual reporting and are subject to re-evaluation. Based on the evolving data and development plans for our product candidates and changing incidence and prevalence rates for our intended indications, there can be no guarantee that we will be able to successfully maintain our orphan drug designations for any of our products.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes FDA or EMA from approving another marketing application for the same drug or biologic for that time period. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another product that meets the definition of a “same drug” under 21 C.F.R. 316.3 for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA exercises its authority to revoke orphan drug designation, which it may do on a variety of grounds, including that the request contained an untrue statement of material fact or omitted material information, or that the drug in fact was not eligible for orphan drug designation. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek 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 or obtain orphan drug exclusivity. In addition, the U.S. Orphan Drug Act may be subject to amendments that could reduce the period of marketing exclusivity or change the qualifications for orphan drug designation, which could adversely impact our products or product candidates that have or may be eligible for orphan drug designation.

We are conducting clinical trials, and anticipate additional clinical trials, for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

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

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

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

We have product candidates still under development and are also preparing for commercial manufacturing activities, and as such clinical and commercial manufacturing site additions, scale-up and process improvements implemented in the production of those product candidates may affect their ultimate activity or function.

Many of our product candidates are currently manufactured in relatively small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity and/or analytical profile of the product 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 the Phase 3 study and materials from more than one manufacturing process were utilized in the Phase 3 UNITY-CLL trial and the Phase 3 ULTIMATE I and II trials. 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 may also 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 conduct additional analyses of the Phase 3 study(ies) to confirm that there is no difference in safety or efficacy between the product made by each process in order to 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 that there are no clinical differences between these drug products, which could substantially impact the approvability of the combination of UKONIQ and ublituximab 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.

We have engaged a secondary manufacturer for ublituximab to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for UKONIQ to meet expanded clinical trial and projected 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 UKONIQ as manufactured to date and used in currently available pre-clinical data and or in 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, with the FDA approval of UKONIQ and as we move closer to commercialization of ublituximab, we are scaling-up production to ensure adequate commercial supply. 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 an 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 Governmental Regulation of Pharmaceutical Industry and Legal Compliance Matters

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

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

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

Beyond the ACA, there has been increasing legislative, regulatory and enforcement interest with respect to prescription drug pricing practices. With the election of President Biden and changes in make-up of the Senate following the 2020 election, we face uncertainties with respect to executive and legislative actions relating to drug pricing. Proposals that may garner bipartisan legislative support or become legislation through reconciliation include adding a cap on out-of-pocket spending under Medicare Part D, authorizing Medicare to negotiate certain drugs covered by Medicare Parts D and B directly with manufacturers, and imposing limits on increases in drug prices. In addition, President Biden may take executive action to introduce new drug pricing models and other drug pricing initiatives. The Biden Administration also may propose substantial changes to the U.S. healthcare system, including expanding government-funded health insurance options. We are uncertain of the impact or outcome of potential Executive Orders, rescission of rules and policy statements, or new legislation, especially any relative impact on the healthcare regulatory and policy landscape, or the impact they may have on our business. We expect drug pricing will continue to be a focus of the Biden Administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

At the state level, individual states are experiencing significant economic pressure within their state Medicaid programs and responding to public concern over the cost of healthcare. The economic impact of the COVID-19 pandemic has further exacerbated state budgetary pressures. States, including California, Florida, Nevada and Maine, among others, have responded to these pressures with a range of legislative enactments and policy proposals designed to control prescription drug prices by, for example, allowing importation of pharmaceutical products from jurisdictions outside the U.S., imposing price controls on state drug purchases, consolidating state drug purchasing to a single purchaser, and imposing transparency measures around prescription drug prices and marketing costs. These measures, which vary by state, could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing.

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

Furthermore, legislative and regulatory proposals have been made to expand post-approval requirements 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 Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

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

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

With the FDA approval of UKONIQ in February 2021, we became subject to additional extensive healthcare statutory and regulatory requirements and oversight by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our past, current and future relationships, arrangements and interactions with these professionals and entities, as well as with patients and patient advocacy organizations will 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 so-called federal “Sunshine Act” under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to monitor and report information related to payments and other transfers of value to and the ownership and investment interests of physicians and teaching hospitals (and additional categories of healthcare providers beginning with reports submitted in 2022) to the federal government for redisclosure to the public;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
- the Federal Food, Drug, and Cosmetic Act and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;

- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the Drug Supply Chain Security Act, or DSCSA, which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the U.S.; and
- state law equivalents of some of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In the U.S., to help patients who have no or inadequate insurance coverage of UKONIQ, we have a patient support program that we administer in conjunction with a patient support program vendor and other third parties. There has been heightened governmental scrutiny over the scope of patient support programs and the manner in which drug manufacturers and their vendors operate such programs. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws, regulations, or evolving government guidance on patient support programs. A government investigation, regardless of its outcome, could impact our business practices, harm our reputation, divert attention of management, increase our expenses and reduce availability of assistance to patients. If we or our vendors are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations will 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. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Advisory Opinions, and Special Fraud Alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the AKS are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including 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, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations.

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

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the United States, various federal and state laws regulate the privacy and security of personal information and so may affect our business operations. For example, at the federal level, our operations may be affected by the data privacy and security provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations. Although we are not currently directly subject to HIPAA, HIPAA affects the ability of healthcare providers and other entities with which we may interact, including clinical trial sites, to disclose patient health information to us. Under Section 5(a) of the Federal Trade Commission Act, or the FTCA, the FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce

vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act, or the CCPA, went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information.

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

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

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

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

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

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the indicated uses for which the drug may be marketed or to conditions of approval that may require potentially costly post-marketing clinical trials or surveillance to monitor safety and efficacy of the drug candidate. In addition, any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA 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, and requirements regarding promotional interactions with healthcare professionals.

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

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

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

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

Our third-party manufacturers may use hazardous materials in the production of UKONIQ and our product candidates and if so, they must comply with environmental laws and regulations, which can be expensive and restrict how we or they do business.

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

Risks Related to Our Dependence on Third Parties

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

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

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

Whether conducted through a CRO or through our internal staff, we are solely responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or other enforcement actions that may include civil penalties 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 drug candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, clinical investigators, CROs, institutional review boards, and non-clinical laboratories. If we, our CROs, our investigators or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our CROs or CMOs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory

approval process and could also subject us to enforcement action. We also are required to register most ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, e.g., ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture, packaging and labeling of any products that we commercialize, including UKONIQ, and our product candidates for pre-clinical development and clinical testing. In some circumstances, our licensor has entered into arrangements with contract manufacturers to supply product for our clinical and commercial demand. Our reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

For certain of our product candidates, we do not have long-term supply agreements with contract manufacturers. For these product candidates, we purchase our required drug supply, including the drug product and drug substance on a purchase order basis. We may be unable to establish or maintain agreements with third-party manufacturers for these products or product candidates or do so on acceptable terms. No assurance can be given that long-term, scalable manufacturers can be identified or that they can make clinical and commercial supplies of our product candidates that meet the product specifications of previously manufactured batches, or are 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 or supply agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

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

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, or interrupt commercial distribution. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our products or product candidates could result in significant delays or gaps in availability of such products or product candidates 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 rely on other third parties to store and distribute drug supplies for our clinical trials and for commercial demand for UKONIQ and expect to continue to do so for any other product candidates that may receive approval. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any future product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

The third parties upon whom we rely for the supply of starting materials, intermediates, active pharmaceutical ingredient (API)/drug substance, drug product, and other materials used in our drug candidates are our sole source of supply, and the loss or disruption of any of these suppliers, including as a result of the COVID-19 pandemic, could significantly harm our business.

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

Although COVID-19 has not had a material adverse effect on our supply chain to date, no assurance can be given that it will not in the future if the situation persists or worsens. UKONIQ is manufactured in India, ublituximab is manufactured in South Korea, and TG-1701 is manufactured in China. Each of these countries continues to be, or has been, subject to government-imposed quarantines and travel restrictions due to the COVID-19 pandemic, which, in some cases, have resulted in reduced operations at manufacturing and research locations and time-limited shutdowns. India, for example, experienced a surge of Covid-19 infections in April and May 2021. Our contract manufacturers for UKONIQ and ublituximab are continuing operations at varying levels of capacity. We have worked closely with our contract manufacturer for UKONIQ to plan for anticipated commercial supply needs. We also are working closely with our contract manufacturer for ublituximab to plan for our anticipated commercial supply needs if we are successful in obtaining FDA approval of the product. We will continue to monitor the situation very closely with our suppliers in impacted regions.

We continually evaluate our supply chains to identify potential risks and needs for additional manufacturers and other suppliers for the production of our products and product candidates. Establishing additional or replacement suppliers for the API/drug substance and drug product, if required, may not be accomplished quickly or at all and may involve significant expense. If we are able to find a replacement supplier, we would need to evaluate and qualify such replacement supplier and its ability to meet quality and compliance standards. Any change in suppliers or the manufacturing process could require additional regulatory approval and result in operational delays. While we seek to maintain adequate inventory

of materials necessary for the production of our products and product candidates, any supply interruption or delay, or our inability to identify alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our commercialization and development efforts, which could harm our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

We 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 product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

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

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

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 product 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. If the scope of our patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to any product we commercialize, including UKONIQ, our product candidates, their formulations and uses and the methods we use to manufacture them, as well as successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and

by maintenance of our trade secrets through proper procedures. Because we in-license our products and product candidates, we also rely on our licensors to protect the patent and other intellectual property rights necessary for commercialization.

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

Currently, the composition of matter patent for ublituximab and UKONIQ are granted in both the United States and EU, among other countries. A method of use patent covering the combination of ublituximab and UKONIQ has also been granted in the United States, Europe, Japan, and several other territories. Additionally, several method of use patents for ublituximab and UKONIQ 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 cosibelimab, TG-1701 and TG-1801 or for our pre-clinical product candidates will be granted in any or all jurisdictions in which they 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 licensors 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 products or 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 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 products or product candidates, our ability to develop and commercialize such drugs may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to 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 U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a third-party.

In addition, U.S. patent laws may change, which could prevent or limit us, our subsidiaries, or our licensors from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include 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 U.S. patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by patents and patent applications for our drug candidates is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Even if our patent applications issue as patents, and they are unchallenged, our issued patents and 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 products or product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products or product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our products or product candidates could be negatively affected, which would harm our business.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we have entered into agreements with many of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology 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 products and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

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

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

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

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

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

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

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

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

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

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

Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our resources and attention from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which typically are very expensive, time-consuming and disruptive 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 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. If we decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, as courts or patent offices in the United States and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing

evidence as to the invalidity of the patent's claims. If we are unable to do so, we may be forced to delay the launch of our product candidates or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

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

No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering 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.

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 Our Business Organization and Governance, Strategy, Employees and Growth Management

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

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

We expect to continue hiring qualified personnel across a range of functions, including development and commercialization. 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 products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. 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 significantly impede 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.

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

Expanding our business will increase our operating needs. As of September 30, 2021, we had 365 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, commercial, and scientific personnel, systems and facilities currently in place may not be adequate to support our anticipated 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 advance the commercialization of UKONIQ and further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $956.3 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 Tax Act, we may not use net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. On March 27, 2020, the "CARES Act" was signed by the U.S. President. Certain provisions of the CARES Act alter the rules regarding net-operating losses for such losses arising in 2018, 2019 and 2020. Such losses may be carried back for five years. We cannot assure you, however, of our ability to utilize these favorable offset rules within the applicable time period. These rules apply regardless of the occurrence of an ownership change.

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

Certain of our executive officers, directors and stockholders own more than 10% of our outstanding common stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

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

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the COVID-19 pandemic has caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

On January 31, 2019 (Brexit Day), the United Kingdom formally left 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. Although the United Kingdom and the European Union reached a trade agreement in late 2020, the long-term impact of Brexit, including on our business and our industry, remains uncertain. 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 employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, principal investigators, CROs, CMOs, and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics applicable to all of our employees and have implemented a compliance program, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged

risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, regardless of the outcome, our reputation and our business may suffer. If we are not successful in defending ourselves or asserting our rights, those actions could lead to imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business.

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

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

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

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

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

Risks Related to the COVID-19 Pandemic

Major public health issues, and specifically the pandemic caused by COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.

In December 2019, a novel strain of coronavirus which causes a disease referred to as COVID-19, was first detected in Wuhan, China, and has since spread around the world. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID-19 outbreak had evolved into a pandemic. In response to the pandemic, many governments around the world have implemented a variety of control measures to reduce the spread of COVID-19, including travel restrictions and bans, instructions to residents to practice social distancing, quarantine advisories, shelter-in-place orders and required closures of non-essential businesses.

The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. Although COVID-19 has not had a material adverse effect on our business to date, no assurance can be given that it will not in the future if the situation persists or worsens. The extent to which the COVID-19 pandemic impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the, the rate of vaccination and efficacy of approved vaccines against the virus and any variant strains of the virus, other actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume if and when the pandemic subsides, among others.

Should the COVID-19 pandemic persist or worsen and government restrictions continue, our business operations could be materially delayed or interrupted. For instance, our ongoing clinical trials may be delayed or compromised; our ability to conduct new clinical trials may be adversely impacted; our supply chain may be disrupted; health authority inspections of clinical sites or manufacturing facilities, or review of our regulatory submissions may be delayed, and our commercialization efforts may be impacted. For example, during the course of the pandemic the FDA has at points delayed both domestic and foreign facility inspections. The agency announced in July 2020 that domestic facility inspections would be conducted but prioritized through a risk-based approach, while foreign facility inspections remained delayed unless the FDA determines they can be conducted based on a "mission-critical" assessment. More recently, in April 2021, the FDA announced that it may request to conduct "remote interactive evaluations," which in a variety of circumstances are inclusive of Pre-Approval Inspections (PAIs), where it is determined to be appropriate based on risk management methods and related tools and any travel limitations. We expect the impact of COVID-19 on the FDA's operations will continue to evolve. It is unknown how long these disruptions could continue, were they to occur. Any delay in our clinical trials, PAIs or in the regulatory review of our pending BLA submission for ublituximab resulting from such disruptions could materially affect the development and commercialization of our product candidates.

We currently rely on third parties for certain functions or services in support of our clinical trials and key areas of our operations. These third parties include contract research organizations (CROs), medical institutions and clinical investigators, contract manufacturing organizations, suppliers, and external business partners supporting commercialization of UKONIQ. If these third parties themselves are adversely impacted by restrictions resulting from the COVID-19 outbreak, we will likely experience delays and/or realize additional costs. As a result, our efforts to commercialize UKONIQ and obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or disrupted.

In addition, to protect the health of our workforce, starting in March 2020 we asked our office-based employees to work remotely. Although many of the social distancing guidelines and capacity restrictions have been lifted, our office-based employees have continued to work remotely as we plan for office reopening. Third parties on which we rely may also be continuing to use remote working arrangements that they had implemented in response to COVID-19. Our increased reliance on personnel working remotely may negatively impact productivity, including our ability to monitor clinical trials, prepare regulatory applications, and conduct data analysis, or disrupt, delay, or otherwise adversely impact our business. In addition, remote working could increase our cybersecurity risk and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, manufacturing sites, research or clinical trial sites and contractors.

Our ability to successfully commercialize UKONIQ, and any of our product candidates for which we in the future obtain regulatory approval, also may be adversely impacted by restrictions and safety measures instituted due to COVID-19. For example, reduced access to healthcare providers and institutions as a result of COVID-19 safety protocols has impacted our commercialization activities, including, the manner in which our field teams engage with healthcare providers and facilities. Our compliance monitoring and oversight of interactions and communications with HCPs, payors, and other stakeholders also has been impacted by the remote work environment.

The potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict. However, it has already caused, and is likely to result in further, significant disruption of global financial markets. It is likely that the pandemic will cause an economic slowdown of potentially extended duration, and it is possible that it could cause a global recession. This disruption may reduce our ability to access capital either at all or on favorable terms. In

addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material adverse effect on our business, financial condition and results of operations.

To the extent the COVID-19 pandemic materially adversely affects our business and financial results, it may also have the effect of significantly heightening many of the other risks described in this Risk Factors section.

The COVID-19 pandemic could have a material adverse effect on our clinical development program if the pandemic and associated government control measures continue.

The ongoing COVID-19 pandemic has presented substantial public health challenges and is impacting the global healthcare system, including the conduct of clinical trials in the U.S. and other parts of the world. While global infection rates have significantly reduced from their peak during 2020, new variants continue to circulate, and uncertainty remains as to whether additional restrictions may be implemented to address the spread of new variants. As a result of the COVID-19 pandemic, we may encounter delays in our clinical development program. The majority of our clinical trials involve patients with cancer or those receiving ongoing immunosuppressive therapy who may be at higher risk of infection. These patients are thus more likely to be subject to travel restrictions and self-quarantining and may be more likely to withdraw from our clinical trials or unable to complete study assessments, which may affect our ability to meet our projected timelines.

Further, we may not be able to complete our clinical trials that we initiated more recently and for which we have not yet completed enrollment in the time frame that we had previously planned. In addition, the pandemic may adversely affect our ability to conduct new trials. Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our clinical trial programs, as well as adversely impact our business generally, include:

- delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical sites, impacts on compliance with clinical study protocols, delays enrolling patients in our clinical trials, decreased enrollment in our clinical trials or increased rates of patients withdrawing from our clinical trials following enrollment, in each case, as a result of patients contracting COVID-19, being forced to quarantine, experiencing reluctance to seek medical attention in a healthcare facility setting, or otherwise not being able or willing to complete study assessments, particularly for older patients or others with a higher risk of contracting COVID-19;
- impacts to clinical results, including an increased number of observed adverse events, as a result of participants enrolled in our clinical trials contracting COVID-19;
- prioritization by healthcare providers, facilities, lawmakers, and regulators of COVID-19-related healthcare needs or, when the pandemic subsides, to address the potential backlog of patients who have deferred medical procedures during the pendency of the pandemic, which may reduce availability of professionals and resources for clinical trials in other disease areas;
- limitations on travel, including limitations on domestic and international travel, and government-imposed quarantines or restrictions imposed by key third parties that could interrupt key trial activities, such as clinical trial site initiations and monitoring, which could impact the reliability or integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages or interruption in global shipping that may affect the transport of clinical trial materials;
- disruptions and delays caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home across the healthcare system;
- disruptions in or delays to regulatory reviews, responses, inspections, or other regulatory activities, including review of marketing applications and approvals of protocol changes or amendments to SPAs, as a result of the spread of COVID-19 affecting the operations of the FDA or other regulatory authorities;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States; and
- negative effects on the quality, completeness, integrity, interpretability and cost of our clinical study data.

The potential disruptions discussed above and other consequences of the COVID-19 pandemic could result in missed study visits or study procedures in our clinical trials, which could lead to an abundance of protocol deviations that impact the interpretability of the trial results. A significant number of deviations may call into question whether the execution of a clinical trial was consistent with the protocol, which is of particular importance where study designs were agreed to as part of a SPA as in the case of our Phase 3 clinical trial for the combination of ublituximab plus UKONIQ for patients with CLL (UNITY-CLL) and our registration program for ublituximab in RMS (ULTIMATE I and II). In extreme cases, significant deviations from the protocol may be considered a violation of the SPA and result in potential rescindment of the SPA agreement, which could adversely affect our ability to use the results of the impacted study to support a future regulatory application.

We will continue to monitor the potential impact of COVID-19 on our clinical trial program, however, the full extent to which the COVID-19 pandemic may directly or indirectly impact the progress of our current and planned trials will depend on future developments that are highly uncertain and cannot be accurately predicted.

General Risks

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

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

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

- 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 such as the disruptions in the global economy caused by the COVID-19 pandemic;
- period-to-period fluctuations in our revenues and other results of operations;
- failure to meet our revenue projections or guidance;
- changes in financial estimates by securities analysts; and
- sales of our common stock by us.

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

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

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. Furthermore, the terms of any future debt agreements may continue to preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

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

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

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. 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 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 over financial reporting, which could have an adverse effect on the market price of our stock.

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

In the past, securities class action and shareholder derivative litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. Past lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits, 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.

ITEM 6. EXHIBITS

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 8, 2021.
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 8, 2021.
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 8, 2021.
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 8, 2021.
101*	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, 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 Changes in Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
** Furnished herewith.

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 8, 2021

By: /s/ Sean A. Power
Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Weiss, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

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

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean A. Power, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2021

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

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF

TG THERAPEUTICS, INC.

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chairman and 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, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2021

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

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF

TG THERAPEUTICS, INC.

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Sean A. Power, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2021

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