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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, 2026

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.)

3020 Carrington Mill Blvd, Suite 475
Morrisville, North Carolina 27560
(Address including zip code of principal executive offices)

(877) 575-8489
(Registrant's 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 pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
☒ Yes ☐ No ☐

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

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

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

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

There were 151,147,827 shares of the registrant's common stock, $0.001 par value, outstanding as of November 4, 2026.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2026

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this Quarterly Report on Form 10-Q contain forward-looking statements. All statements other than statements of historical facts may constitute forward-looking statements. We intend such forward-looking statements to be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements 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. Such forward-looking statements include, but are not limited to, statements about:

- our ability to obtain regulatory approvals for our product candidates, including a subcutaneous (SubQ) formulation of ublituximab and azer-cel, and our ability to maintain regulatory approval of BRIUMVI® (ublituximab-xiiy) 150 mg/6 mL Injection for intravenous therapy for the treatment of relapsing forms of multiple sclerosis (RMS) or any other future indication in the United States (U.S.) or any other jurisdiction outside of the U.S.;
- our ability to adapt and expand our commercial infrastructure to successfully, or in the timeframe projected, market and sell BRIUMVI and our product candidates;
- our ability to maintain a reliable supply of our products that meets market demand;
- the timing and success of the ongoing commercialization and availability of BRIUMVI or any future products or combinations of products, including the anticipated rate and degree of market acceptance and pricing and reimbursement;
- the initiation, timing, progress and results of our preclinical studies and clinical trials;
- our ability to advance drug candidates into, and successfully complete, clinical trials;
- our ability to develop, formulate, manufacture and commercialize our product candidates;
- our ability to establish and maintain contractual relationships and partnerships, on commercially reasonable terms, with third parties for manufacturing, distribution, marketing and supply and a range of other support functions for our clinical development and commercialization efforts;
- the implementation of our business model and strategic plans for our business and drug candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product and product candidates;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations and enter into strategic arrangements, if desired;
- our ability to meet any of our financial projections or guidance, including, without limitation, short- and long-term revenue and operating expense projections or guidance and changes to the assumptions underlying those projections or guidance;
- our ability to obtain sufficient capital to fund our planned operations;
- our financial performance and cash burn management;
- our ability to maintain or obtain adequate product liability and other insurance coverage;
- developments relating to our competitors and our industry;
- the effects on our company of future regulatory developments or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject, including tariffs that may apply to products that we purchase or sell;
- prevailing economic, market and business conditions;
- our ability to retain, attract and hire key personnel;
- our competitive position;
- fluctuations in the trading price of our common stock;
- our use of cash and other resources; and
- our ability to successfully implement our strategy.

Forward-looking statements are not guarantees of performance. They involve risks, uncertainties and assumptions. You should refer to the "Risk Factors" section in this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Although we make such statements based on assumptions that we believe to be reasonable, there can be no assurance that actual results will not differ materially from our expectations. We caution you not to rely unduly on any forward-looking statements.

These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

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 discussed in the section entitled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and any other risks described in the other reports and documents that we have filed with the Securities and Exchange Commission (SEC).

Risks Related to Commercialization

- If BRIUMVI or any product candidate for which we obtain marketing approval from the United States (U.S.) Food and Drug Administration (FDA) or any comparable regulatory authority outside of the U.S. does not achieve or maintain broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from product sales will be limited.
- We may be subject to limitations on the indicated uses or requirements to fulfill certain post-marketing requirements or commitments to the satisfaction of regulatory authorities or may be unable to maintain marketing approval for BRIUMVI or future products that we may bring to market.
- BRIUMVI, and any of our product candidates for which we in the future obtain marketing approval, may, after approval, be found to cause undesirable side effects that could result in significant negative consequences following commercialization.
- The incidence and prevalence for target patient populations of BRIUMVI and our product candidates have not been established with precision. If the market opportunities for BRIUMVI and our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected.
- 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.
- BRIUMVI, as well as any products that we are able to commercialize in the future, may become subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, which would harm our business.
- Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any drug candidates that we may develop.

Risks Related to Our Financial Position and Need for Additional Capital

- We have a history of losses and our ability to maintain profitability in the future remains uncertain. We expect to incur significant expenses for the foreseeable future as we commercialize BRIUMVI and advance our product candidates through clinical trials, seek regulatory approvals and pursue commercialization.
- While we do not expect to need to raise additional capital, we may need to do so in the future. If we are unable to raise capital, if needed, we may be required to delay, limit, reduce or eliminate some of our drug development programs or commercialization efforts.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

Risks Related to Drug Development and Regulatory Approval

- If we are unable to maintain or obtain regulatory approval for our product or product candidates and ultimately cannot successfully commercialize our product or product candidates, or experience significant delays in doing so, our business will be materially harmed.
- 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.
- Biologics carry unique risks and uncertainties, which could have a negative impact on our business.
- Our product or product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or impact their availability and commercial potential after approval.
- Any products or product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals.

Risks Related to Governmental Regulation of the Pharmaceutical Industry 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.
- Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.
- 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.
- Any product for which we obtain marketing approval, including BRIUMVI, could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Risks Related to Our Dependence on Third Parties

- We rely on third parties to generate clinical, preclinical and other data necessary to support the regulatory applications needed to conduct clinical trials and submit for marketing approval. We rely on third parties to help conduct our planned clinical trials. If these third parties do not perform their services as required, we may not be able to obtain regulatory approval for or commercialize our product or product candidates when expected or at all.
- We contract with third parties for the manufacture and testing of BRIUMVI for commercial supply, as well as all of our clinical product supply, and we expect to continue to do so. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.
- The third parties upon whom we rely for the supply of starting materials, intermediates, active pharmaceutical ingredient (API)/drug substance, drug product, and other materials used in our drug candidates are our sole source of supply, and the loss or disruption of any of these suppliers could significantly harm our business.
- Because we have in-licensed BRIUMVI and our product candidates from third parties, any dispute with or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product or product candidate.
- We are dependent upon our relationships with collaboration and commercialization partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration or commercialization partner terminates its collaboration or commercialization agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration or commercialization partner to perform its duties under its collaboration or commercialization agreement with us may negatively affect us.

Risks Related to 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. At the same time, if the scope of our patent protection is too broad, our competitors may challenge the validity and enforceability of our patents.
- 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.
- We may not be able to enforce our intellectual property rights throughout the world.
- 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.
- 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 are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

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

- If we fail to attract and keep key management, commercial, and clinical development personnel, we may be unable to successfully develop or commercialize our product and product candidates.
- We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
- 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.
- Our internal information technology systems, or those of our third-party contract research organizations (CROs), contract manufacturing organizations (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.
- Unfavorable global economic conditions and changes in government regulations could adversely affect our business, financial condition or results of operations.

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 our stock at a profit.
- 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.

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 1A 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, 2026	December 31, 2025
	(Unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 429,376	$ 79,148
Short-term investment securities	75,295	62,822
Accounts receivable, net	416,821	305,628
Inventories	194,319	125,586
Other current assets	55,636	57,580
Total current assets	1,171,447	630,764
Restricted cash	1,375	1,342
Long-term investment securities	56,035	59,136
Right of use assets	6,830	6,278
Deferred tax assets	333,383	348,000
Non-current inventories	20,806	15,689
Other noncurrent assets	2,376	2,044
Total assets	$ 1,592,252	$ 1,063,253
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 176,859	$ 107,508
Other current liabilities	1,222	2,124
Lease liability – current portion	1,844	1,044
Deferred revenue - current portion	26,102	21,234
Accrued compensation	54,499	21,850
Total current liabilities	260,526	153,760
Deferred revenue, non-current portion	7,070	8,807
Loan payable – non-current	745,634	245,645
Lease liability – non-current	6,895	7,021
Total liabilities	$ 1,020,125	$ 415,233
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value per share (190,000,000 and 190,000,000 shares authorized, 160,054,603 and 158,849,596 shares issued, 151,159,605 and 155,305,953 shares outstanding at September 30, 2026 and December 31, 2025, respectively)	160	159
Additional paid-in capital	1,871,185	1,830,110
Treasury stock, at cost, 8,894,998 and 3,543,643 shares at September 30, 2026 and December 31, 2025, respectively	(300,224)	(100,234)
Accumulated deficit	(998,994)	(1,082,015)
Total stockholders' equity	572,127	648,020
Total liabilities and stockholders' equity	$ 1,592,252	$ 1,063,253

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,	
	2026	**2025**	**2026**	**2025**
Revenue:				
Product revenue, net	$ 240,043	$ 159,317	$ 677,145	$ 417,815
License, milestone, royalty and other revenue	19,893	2,392	28,044	5,898
Total revenue	$ 259,936	$ 161,709	$ 705,189	$ 423,713
Costs and expenses:				
Cost of revenue	42,079	28,093	116,783	62,572
Research and development:				
Stock-based compensation	7,550	5,335	20,495	12,984
Other research and development	43,740	35,543	174,528	106,038
Total research and development	51,290	40,878	195,023	119,022
Selling, general and administrative:				
Stock-based compensation	17,153	12,351	52,033	36,035
Other selling, general and administrative	63,515	51,022	198,982	133,254
Total selling, general and administrative	80,668	63,373	251,015	169,289
Total costs and expenses	174,037	132,344	562,821	350,883
Operating income	85,899	29,365	142,368	72,830
Other expense (income):				
Interest expense	15,819	6,721	40,057	20,194
Loss on extinguishment of debt	—	—	9,153	—
Other income	(3,782)	(3,265)	(11,301)	(9,661)
Total other expense	12,037	3,456	37,909	10,533
Net income before taxes	$ 73,862	$ 25,909	$ 104,459	$ 62,297
Income tax (expense) benefit	(18,399)	364,986	(21,438)	361,845
Net income	$ 55,463	$ 390,895	$ 83,021	$ 424,142
Net income per common share				
Basic	$ 0.39	$ 2.69	$ 0.58	$ 2.90
Diluted	$ 0.35	$ 2.43	$ 0.52	$ 2.62
Weighted-average shares of common stock outstanding				
Basic	140,786,274	145,416,901	142,318,594	146,273,554
Diluted	155,925,050	160,997,977	157,741,254	162,102,373

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

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

	Common Stock		Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at January 1, 2025	156,204,159	$ 156	$ 1,760,396	367,903	$ (8,994)	$ (1,529,194)	$ 222,364
Issuance of common stock in connection with exercise of options	5,000	*	20	—	—	—	21
Issuance of restricted stock	2,547,179	2	(2)	—	—	—	—
Forfeiture of restricted stock	(20,052)	*	*	—	—	—	—
Purchase of Treasury Stock	—	—	—	199,695	(6,123)	—	(6,123)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	15,967	—	—	—	15,967
Net income	—	—	—	—	—	5,060	5,060
Balance at March 31, 2025	158,736,286	$ 159	$ 1,776,381	567,598	$ (15,117)	$ (1,524,134)	$ 237,289
Issuance of common stock in connection with exercise of options	46,650	*	432	—	—	—	432
Issuance of restricted stock	176,467	*	*	—	—	—	—
Forfeiture of restricted stock	(173,068)	*	*	—	—	—	—
Purchase of Treasury Stock	—	—	—	193,500	(6,875)	—	(6,875)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	17,399	—	—	—	17,399
Net income	—	—	—	—	—	28,187	28,187
Balance at June 30, 2025	158,786,335	$ 159	$ 1,794,212	761,098	$ (21,992)	$ (1,495,947)	$ 276,432
Issuance of restricted stock	11,000	*	*	—	—	—	—
Forfeiture of restricted stock	(43,159)	*	*	—	—	—	—
Purchase of Treasury Stock	—	—	—	2,782,545	(78,242)	—	(78,242)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	18,133	—	—	—	18,133
Net income	—	—	—	—	—	390,895	390,895
Balance at September 30, 2025	158,754,176	$ 159	$ 1,812,345	3,543,643	$ (100,234)	$ (1,105,052)	$ 607,218

	Common Stock		Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at January 1, 2026	158,849,596	$ 159	$ 1,830,110	3,543,643	$ (100,234)	$ (1,082,015)	$ 648,020
Issuance of common stock in connection with exercise of options	131,000	*	763	—	—	—	763
Issuance of restricted stock	1,047,977	1	(1)	—	—	—	—
Forfeiture of restricted stock	(63,148)	*	*	—	—	—	—
Purchase of Treasury Stock	—	—	—	3,327,903	(99,992)	—	(99,992)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	14,563	—	—	—	14,563
Net income	—	—	—	—	—	19,777	19,777
Balance at March 31, 2026	159,965,425	$ 160	$ 1,845,435	6,871,546	$ (200,226)	$ (1,062,238)	$ 583,131
Issuance of common stock in connection with exercise of options	13,660	*	85	—	—	—	85
Forfeiture of restricted stock	(29,755)	*	*	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	13,086	—	—	—	13,086
Net income	—	—	—	—	—	7,781	7,781
Balance at June 30, 2026	159,949,330	$ 160	$ 1,858,606	6,871,546	$ (200,226)	$ (1,054,457)	$ 604,083
Issuance of common stock in connection with exercise of options	36,000	*	252	—	—	—	252
Issuance of common stock in connection with cashless exercise of warrants	114,525	*	*	—	—	—	—
Forfeiture of restricted stock	(45,252)	*	*	—	—	—	—
Purchase of Treasury Stock	—	—	—	2,023,452	(99,998)	—	(99,998)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	12,327	—	—	—	12,327
Net income	—	—	—	—	—	55,463	55,463
Balance at September 30, 2026	160,054,603	$ 160	$ 1,871,185	8,894,998	$ (300,224)	$ (998,994)	$ 572,127

* *Amount less than one thousand dollars*

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

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

	Nine months ended September 30,	
	2026	**2025**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 83,021	$ 424,142
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Loss on extinguishment of debt	9,153	—
Stock-based compensation	72,528	49,019
Depreciation and amortization	158	38
Amortization of discount on investment securities	(835)	(3,405)
Amortization of debt issuance costs	779	912
Amortization of leasehold interest	137	139
Deferred income taxes	14,617	(366,627)
Noncash change in lease liability and right of use asset	1,458	1,316
Change in fair value of equity investments	(1,391)	(135)
Change in fair value of notes payable	649	163
Changes in assets and liabilities:		
Increase in inventory	(70,600)	(34,015)
Decrease (increase) in other current assets	9,963	(40,519)
Increase in accounts receivable	(111,193)	(136,199)
Decrease in income taxes payable	(10,372)	(2,584)
Increase in accounts payable and accrued expenses	68,282	56,454
Decrease in lease liabilities	(1,335)	(1,580)
Decrease in other current liabilities	(1,555)	(2,647)
Increase in deferred revenue	3,132	11,096
Net cash provided by (used in) operating activities	66,596	(44,432)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of held-to-maturity securities	44,000	207,500
Investment in held-to-maturity securities	(49,878)	(176,666)
Purchases of equity investments	(1,000)	(1,250)
Purchases of property, plant and equipment	(626)	(147)
Net cash (used in) provided by investing activities	(7,504)	29,437
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of loan payable	(255,000)	—
Proceeds from exercise of options	1,101	453
Proceeds from debt financings, net of debt discount costs	747,656	—
Financing costs paid	(2,598)	—
Purchase of treasury stock	(199,990)	(91,240)
Net cash provided by (used in) financing activities	291,169	(90,787)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	350,261	(105,782)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	80,490	181,192
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 430,751	$ 75,410
Reconciliation to amounts on condensed consolidated balance sheets:		
Cash and cash equivalents	$ 429,376	$ 74,081
Restricted cash	1,375	1,329
Total cash, cash equivalents and restricted cash	$ 430,751	$ 75,410
Cash paid for:		
Interest	$ 35,900	$ 18,339
Income taxes	$ 17,192	$ 7,034
NONCASH TRANSACTIONS		
Reduction of lease liability and right-of-use asset due to lease modification	$ 1,126	$ —

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 its subsidiaries.

NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

TG Therapeutics is a fully integrated, commercial-stage biotechnology company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline, TG Therapeutics has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI (ublituximab-xiiy) to treat adult patients with relapsing forms of multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval from several regulatory agencies outside of the U.S. for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features. The Company also actively evaluates 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 annual 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The accompanying condensed balance sheet as of December 31, 2025 has been derived from these statements. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Liquidity and Capital Resources

Although the Company has recently achieved profitability, the Company has incurred substantial operating losses since its inception and may continue to experience fluctuations in operating results. Despite the commercialization of BRIUMVI and the potential future commercialization of other product candidates, there can be no assurance that the Company will maintain profitability on an ongoing basis.

For the nine months ended September 30, 2026, the Company generated revenue of $705.2 million and generated operating income and positive cash flows from operations. The Company will continue to invest in its research and development programs and in selling, general and administrative activities to support its commercialization efforts, while maintaining discipline around overall expense growth relative to revenue. The Company's operating results and cash flows have fluctuated in the past and may continue to vary significantly from period to period. The Company will need to generate substantial revenues to sustain profitability and positive cash flow over the long term.

As of September 30, 2026, the Company's accumulated deficit was approximately $1.0 billion, and the Company had $556.7 million in cash and cash equivalents, and investment securities, excluding equity investments. Based on its current operating plan and results, the Company anticipates that its existing cash, cash equivalents, and investment securities, together with projected future revenues, will be sufficient to fund operations and meet its liquidity needs for more than twelve months after the date of filing of this Quarterly Report on Form 10-Q.

The actual level of cash required for operations will depend on numerous factors, including, among others, the scope of commercialization activities for BRIUMVI, the timing of collection of receivables from the Company's customers on extended payment terms, the timing and design of clinical trials for the Company's product candidates, and the costs associated with licensing or acquiring new product candidates. The Company does not currently expect to need to raise additional capital to fund its ongoing operations, but may from time to time seek additional financing to support strategic initiatives, including potential business development activities.

The Company's common stock is listed on the Nasdaq Capital Market under the symbol "TGTX."

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, investments and accounts receivable. The Company maintains its cash and cash equivalents and investments with high-credit quality financial institutions. At times, such amounts may exceed federally insured limits, and the Company monitors the creditworthiness of these institutions on an ongoing basis. We are also potentially subject to concentrations of credit risk in our accounts receivable with respect to amounts owed by a limited number of entities comprising our customer base. Our exposure to credit losses is low, however, owing largely to the credit quality of our distributors.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 1 - Organization and Summary of Significant Accounting Policies to the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, except as updated herein or as it relates to revenue recognition, accounts receivable, inventory, cost of revenue, income taxes, equity securities, and the adoption of new accounting standards during the nine months ended September 30, 2026. Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

The Company monitors new accounting pronouncements issued by the Financial Accounting Standards Board (FASB). Management evaluates, and continues to monitor, recently issued but not yet effective accounting pronouncements and does not expect the adoption of such standards to have a material impact on the Company's consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (ASU 2024-03). ASU 2024-03 requires entities to provide additional disaggregated disclosures of certain income statement expenses, including employee compensation, depreciation, and amortization, within the notes to the financial statements. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The guidance may be applied either prospectively or retrospectively. The Company is currently evaluating the impact that adoption of this new accounting guidance will have on its financial statements.

Revenue Recognition

Pursuant to Topic 606, the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration the Company expects to be entitled to 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, the Company assesses the goods or services promised within each contract and determines which promised good or service is distinct and therefore considered a performance obligation. The Company then recognizes 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, commercial payor 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 for variable consideration are calculated using 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 requirements, customer channel mix, changes to product price, government pricing calculations, and industry data. The amount of variable consideration included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

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

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

Commercial Payor Rebates: The Company contracts with various private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates tied to utilization of its product and contracted formulary status. These rebates are estimated and recorded 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 applicable contracts and are recorded in the period the related product revenue is recognized. In addition, the Company 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 customers and records this estimate in the period the related product revenue is recognized. The Company currently estimates product return liabilities based on data from similar products and other qualitative considerations, such as visibility into the inventory remaining in the distribution channel.

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

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

To date, the Company has experienced an immaterial amount of product returns related to sales of BRIUMVI.

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

License Agreements

The Company generates revenue from license or similar agreements with pharmaceutical companies for the development and commercialization of certain products. Such agreements may include the transfer of intellectual property rights in the form of licenses. Payments made by the customer may include non-refundable upfront fees, payments based upon the achievement of defined milestones, and royalties on sales of products.

Licenses of intellectual property: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. All other promised goods or services in the agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

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

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

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

Other Revenue

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

Deferred Product Revenue

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

Accounts Receivable

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns, and chargebacks. The Company's standard payment terms for invoiced amounts typically range between 30 – 60 days, however, extended payment terms have been offered during the BRIUMVI commercial launch. The extended payment terms are meant to align with the timing of reimbursement by government and commercial payors and have not adversely affected the collectability of accounts receivable.

In addition, the Company does not adjust accounts receivable for the effects of financing, as the expected time between transfer of the promised products and the payment of the associated consideration is less than one year. The Company analyzes accounts that are past due for collectability and regularly evaluates the creditworthiness of its customers so that it can properly assess and respond to changes in their credit profiles. As of September 30, 2026, the Company determined that an allowance for expected credit losses related to outstanding accounts receivable was not required because outstanding receivables were due from large, established, creditworthy customers.

Cost of Revenue

Cost of revenue consists primarily of royalties owed to the Company's licensing partner for BRIUMVI sales, third-party manufacturing costs, distribution, and overhead. Cost of revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All manufacturing costs incurred to produce BRIUMVI prior to the approval of BRIUMVI by the FDA were expensed to research and development and therefore are not reflected in the cost of revenue. Costs related to providing regulatory support and development services to the Company's ex-U.S. commercialization partner, Neuraxpharm, are included in the Company's cost of revenue.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value, with cost based on the first-in-first-out (FIFO) method. The Company classifies inventory costs as non-current inventory in its consolidated balance sheets when the Company expects to utilize the inventory beyond its normal operating cycle. Prior to regulatory approval, the Company expenses 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 are capitalized. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials. Prior to the approval of BRIUMVI, all manufacturing and other potential costs related to the commercial launch of BRIUMVI were expensed to research and development in the period incurred.

Income Taxes

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

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and in various states. The Company has tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination. The Company recognizes interest and penalties related to uncertain income tax positions in income tax expense. Refer to Note 10 – Income Taxes for further information.

Stock-Based Compensation

Stock-based compensation costs related to equity awards granted to employees and non-employees are measured at the date of grant based on the fair value of the award. Equity-classified awards are measured at grant-date fair value and recognized as compensation expense over the requisite service period.

The Company estimates the grant-date fair value of stock options using the Black-Scholes option-pricing model. Awards with market conditions are valued using a Monte Carlo simulation or other appropriate valuation techniques, with the impact of the market condition reflected in the grant-date fair value. The fair value of restricted stock awards is based on the closing price of the Company's common stock on the date of grant.

Compensation expense for time-based awards is recognized on a straight-line basis over the requisite service period. For awards with performance conditions, compensation expense is recognized when it is probable that the performance condition will be achieved. For awards with market conditions, compensation expense is recognized over the derived service period, regardless of whether the market condition is ultimately satisfied. The Company accounts for forfeitures as they occur.

The Company also grants stock tracking units (STUs), which are liability-classified awards that are economically similar to phantom stock. STUs are remeasured at fair value at each reporting date, with changes in fair value recognized as compensation expense in the consolidated statements of operations. Compensation expense for STUs is recognized over the requisite service period, and the related liability is recorded within accrued compensation on the consolidated balance sheet until settlement.

All compensation expense related to these awards is recorded within stock-based compensation expense in the consolidated statements of operations.

Equity Securities

The Company's equity securities consist of the common stock of Precision BioSciences, Inc. (Precision) and Imugene Limited (Imugene). Equity securities are recognized at their fair value in accordance with ASC 321, Investments – Equity Securities. Forward contracts to purchase equity securities that do not qualify as derivatives under ASC 815 are accounted for in accordance with ASC 321. These forward contracts are recorded at fair value at the balance sheet date. See Note 5 - Fair Value Measurements for further details.

Net Income Per Common Share

Basic net income per share of the Company's common stock is calculated by dividing net income applicable to the common stock by the weighted-average number of shares of the Company's common stock outstanding for the period. Diluted net income per share of common stock reflects the effect of potential common shares from the assumed exercise or conversion of securities such as warrants, stock options, and unvested restricted stock awards, to the extent they are dilutive. For all periods presented, the Company reported net income in the condensed consolidated statements of operations and, accordingly, presents the dilutive effect of potential common shares in the computation of diluted earnings per share, as shown in the table below.

The following table summarizes the Company's potentially dilutive securities at September 30, 2026 and 2025:

	As of September 30,	
	2026	**2025**
Unvested restricted stock	11,049,018	11,031,573
Options	4,024,156	4,362,316
Warrants	—	165,214
Shares issuable upon note conversion	23,977	21,973
Stock Tracking Units	41,625	—
Total	15,138,776	15,581,076

The computation of basic and diluted EPS is as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except share and per share data)	**2026**	**2025**	**2026**	**2025**
Net income	55,463	390,895	83,021	424,142
Weighted-average common shares outstanding	140,786,274	145,416,901	142,318,594	146,273,554
Dilutive effect of potential common shares	15,138,776	15,581,076	15,422,660	15,828,819
Weighted-average common shares outstanding assuming dilution	155,925,050	160,997,977	157,741,254	162,102,373
Net income per share - basic	**0.39**	**2.69**	**0.58**	**2.90**
Net income per share - diluted	**0.35**	**2.43**	**0.52**	**2.62**

Segment Reporting

Operating segments are defined as components of an enterprise that engage in business activities from which it may recognize revenues and incur expenses, and for which discrete financial information is available and is evaluated regularly by the chief operating decision maker (CODM) to allocate resources and assess performance.

The Company operates as a single reportable segment, focused on B-cell mediated disease therapy, which includes all activities related to the development and commercialization of novel treatments, including BRIUMVI, to address unmet medical needs and improve the lives of patients. The determination of a single reportable segment is consistent with the consolidated financial information regularly provided to the Company's CODM, which is its chief executive officer, who evaluates financial results and operating metrics, specifically consolidated net income (loss), for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets reported to the CODM corresponds to the total assets presented on the Company's condensed consolidated balance sheet.

NOTE 2 - REVENUE

As discussed in Note 1 - Organization and Summary of Significant Accounting Policies, revenues are recognized under guidance within ASC 606. The following table presents the Company's disaggregated revenue for the periods presented (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Total product revenue, net	$ 240,043	$ 159,317	$ 677,145	$ 417,815
License, milestone, royalty and other revenue	19,893	2,392	28,044	5,898
Total Revenue	$ 259,936	$ 161,709	$ 705,189	$ 423,713

Product Revenue, net

For the three and nine months ended September 30, 2026, product revenue consists of U.S. sales of BRIUMVI of $232.6 million and $655.1 million, respectively. Also included in product revenue for the three and nine months ended September 30, 2026 are sales of BRIUMVI to the Company's ex-U.S. licensing partner, Neuraxpharm, of $7.4 million and $22.0 million, respectively.

As of September 30, 2026 and 2025, gross-to-net accruals recorded as a reduction to accounts receivable, net were $30.7 million and $16.7 million, respectively. Accruals classified as current liabilities within accounts payable and accrued expenses as of September 30, 2026 and 2025 were $70.7 million and $34.9 million, respectively.

The Company primarily sells BRIUMVI through specialty distributors. The following table summarizes the customers that represent 10% or more of gross product revenue for the three and nine months ended September 30, 2026 and 2025:

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Customer 1	46%	47%	43%	43%
Customer 2	26%	24%	27%	27%
Customer 3	17%	17%	18%	17%
Customer 4	10%	11%	10%	12%

The following table summarizes the customers with amounts due that represent 10% or more of the accounts receivable associated with the Company's product sales as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Customer 1	41%	38%
Customer 2	20%	18%
Customer 3	26%	27%
Customer 4	11%	15%

License, Milestone, Royalty and Other Revenue

License, milestone, royalty and other revenue consists primarily of recognition of consideration received under the ex-U.S. commercialization agreement (the Commercialization Agreement) with Neuraxpharm. Refer to Note 9 - License Agreements for a description of the Commercialization Agreement and for further information of the accounting in accordance with ASC 606.

NOTE 3 - INVESTMENT SECURITIES

The Company's investment securities as of September 30, 2026 and December 31, 2025 primarily consist of government debt securities that are classified as held-to-maturity. Held-to-maturity securities are recorded at amortized cost.

The following tables summarize the Company's held-to-maturity securities at September 30, 2026 and December 31, 2025:

	September 30, 2026			
(in thousands)	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term obligations of domestic governmental agencies (maturing between October 2026 and September 2027) (held-to-maturity)	$ 75,295	$ —	$ (232)	$ 75,063
Long-term obligations of domestic governmental agencies (maturing between October 2027 and August 2028) (held-to-maturity)	52,038	—	(613)	51,425
Total held-to-maturity investment securities	$ 127,333	$ —	$ (845)	$ 126,488

	December 31, 2025			
(in thousands)	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term obligations of domestic governmental agencies (maturing between January 2026 and December 2026) (held-to-maturity)	$ 62,822	$ 130	$ —	$ 62,952
Long-term obligations of domestic governmental agencies (maturing between January 2027 and November 2027) (held-to-maturity)	57,541	201	—	57,742
Total held-to-maturity investment securities	$ 120,363	$ 331	$ —	$ 120,694

Included in long-term investment securities on the condensed consolidated balance sheet are equity securities held in connection with the Precision License Agreement and an agreement to purchase Imugene Shares. See Note 5 – Fair Value Measurements for a description of the Precision License Agreement, Imugene Shares, and for further information on the Company's equity investments.

NOTE 4 - INVENTORY

The following table presents the Company's inventory as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Raw Materials	$ 11,171	$ 12,960
Work in Process	181,409	112,397
Finished Goods	28,716	22,089
Inventory, gross	221,296	147,446
Inventory Reserve	(6,171)	(6,171)
Inventory, net	$ 215,125	$ 141,275
Reported As:		
Inventory	$ 194,319	$ 125,586
Non-current Inventory	20,806	15,689
Total Inventory	$ 215,125	$ 141,275

Inventory is stated at the lower of cost or net realizable value and consists of raw materials, work-in-process and finished goods. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Inventory that is used for clinical development purposes is expensed to research and development in the period in which it is consumed.

As of September 30, 2026, the Company's inventory was solely related to BRIUMVI. The work in process materials consist primarily of bulk drug substance, which has a multi-year shelf life. When the bulk drug substance is manufactured into BRIUMVI finished goods, those finished goods have a shelf life of three years from the date of manufacture. The Company expects to sell finished goods at least twelve months prior to expiration. Because a portion of our existing inventory will be utilized beyond our normal operating cycle, $20.8 million of inventory, comprised predominantly of work in process drug substance, is classified as Non-current Inventory at September 30, 2026.

On a quarterly basis, the Company analyzes its inventory levels for excess quantities and obsolescence (expiration) by considering factors such as historical and anticipated future sales relative to quantities on hand and the remaining shelf life. As of September 30, 2026, other than the reserve described below, the Company determined that a reserve related to BRIUMVI inventory for excess quantities and obsolescence was not required. In addition, since FDA approval of BRIUMVI, the Company has not recognized any inventory write downs.

The inventory reserve was $6.2 million at both September 30, 2026 and December 31, 2025 and relates to a manufacturing deviation identified by the Company affecting one batch of bulk drug substance, rendering the batch unsuitable for commercial use.

The United States and other countries have recently imposed, and may continue to impose, new tariffs. Tariffs are an inventoriable cost, and the Company utilizes contract manufacturers of bulk drug substance and drug product located outside of the U.S. Based on currently applicable tariffs, the Company does not expect these costs to have a material impact on its overall gross margin.

NOTE 5 - FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis in its 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 for which market data are not available.

Equity Investments and Forward Contract Liabilities

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

Upon execution of the Precision License Agreement, the Company made an upfront payment to Precision of $7.5 million, comprised of (i) $5.25 million in cash and (ii) $2.25 million (the Upfront Precision Stock Payment), as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock at a price of $0.77 per share. The Company paid a premium for the shares, which was recorded in research and development expense as part of the cost of the Precision License Agreement. Precision subsequently implemented a 30-to-1 reverse stock split in February 2024.

On January 7, 2025, the Company made a one-time payment to Precision equal to $2.5 million (the Deferred Precision Stock Payment), as an equity investment, for the purchase of 220,712 shares of Precision common stock calculated by dividing the Deferred Precision Stock Payment by 200% of the weighted average share price of the Precision common stock for the thirty (30) trading days preceding the payment date. The Deferred Precision Stock Payment, which had previously been classified as a forward contract liability in Other Current Liabilities as of December 31, 2024, was then reclassed to equity investments at its fair market value of $1.4 million on the date the payment was made to Precision.

On February 23, 2026, the Company achieved Milestone Event 1 (as defined in the Precision License Agreement) and made a one-time payment to Precision equal to $7.5 million comprised of (i) $5.25 million in cash and (ii) $2.25 million (the Milestone 1 Stock Payment), as an equity investment, for the purchase of 201,504 shares of Precision's common stock calculated by dividing the Deferred Precision Stock Payment by 200% of the weighted average share price of the Precision common stock for the thirty (30) trading days preceding the payment date. The Milestone 1 Stock Payment, which was classified as a forward contract liability in Other Current Liabilities as of December 31, 2025, was reclassed to equity investments at its fair market value of $0.8 million on the date the payment was made to Precision. The shares purchased with the Milestone 1 Stock Payment, the Upfront Precision Stock Payment and the Deferred Precision Stock Payment are collectively known as the Precision Shares. All Precision Shares are recognized at fair market value as of September 30, 2026, and are classified as an equity investment and included within long-term investments on the condensed consolidated balance sheet as of September 30, 2026.

In July 2026, the Company entered into an agreement to purchase ordinary shares of Imugene Limited (Imugene). In August 2026, the Company paid $1.0 million to purchase 15,789,474 ordinary shares of Imugene at AUD$0.095 per share (the Imugene Shares). The Company is party to a supply agreement with Imugene pursuant to which Imugene provides the Company with certain materials used in the manufacture of azer-cel and shares manufacturing and certain other data pertaining to the development of azer-cel. The Imugene Shares are accounted for under ASC 321, Investments – Equity Securities and are measured at fair value with changes recognized in net income. They are classified as an equity investment and included within long-term investments on the condensed consolidated balance sheet as of September 30, 2026.

The Company has $15.5 million aggregate principal amount of 5% convertible notes outstanding, which are convertible at the option of the holder into common stock at a conversion price of $1,125 per share. The Company does not have a cash repayment obligation associated with these notes. The notes are classified within other current liabilities on the Company's consolidated balance sheet as of September 30, 2026.

The Company's financial instruments include cash, cash equivalents consisting of money market funds, accounts receivable, accounts payable and loan payable. As of September 30, 2026 and December 31, 2025, the fair values of cash and cash equivalents, restricted cash, accounts receivable, and loan and interest payable approximate their carrying values. The carrying value of the loan payable on the Company's balance sheet is estimated to approximate its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics.

The Company's equity investments classified as Level 1 were valued using their respective closing stock prices on the applicable stock exchange, which represent unadjusted quoted prices in active markets for identical instruments. For equity investments denominated in a foreign currency, the fair value is translated into U.S. dollars using the applicable spot exchange rate as of the measurement date. The Company did not experience any transfers of financial instruments between the fair value hierarchy levels during the three months ended September 30, 2026.

The Company's forward contract liabilities classified as Level 2 were valued using Precision's closing stock price on the Nasdaq Stock Market as of December 31, 2025.

The Company's Level 3 instrument amounts represent the fair value of the convertible notes and related accrued interest, as certain inputs to determine fair value were unobservable.

The following tables provide the fair value measurements of applicable financial assets and liabilities as of September 30, 2026 and December 31, 2025:

	Financial assets and liabilities at fair value as of September 30, 2026			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Equity Investments	$ 3,715	$ —	$ —	$ 3,715
Total Assets	$ 3,715	$ —	$ —	$ 3,715
Forward Contract Liabilities	$ —	$ —	$ —	$ —
Convertible notes	—	—	1,337	1,337
Total Liabilities	$ —	$ —	$ 1,337	$ 1,337

	Financial assets and liabilities at fair value as of December 31, 2025			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Equity Investments	$ 1,323	$ —	$ —	$ 1,323
Total Assets	$ 1,323	$ —	$ —	$ 1,323
Forward Contract Liabilities	$ —	$ 1,412	$ —	$ 1,412
Convertible notes	—	—	689	689
Total Liabilities	$ —	$ 1,412	$ 689	$ 2,101

The change in the fair value of the Level 1 assets and Level 2 and Level 3 liabilities is recognized in other (income) expense in the accompanying condensed consolidated statements of operations.

NOTE 6 - STOCK-BASED COMPENSATION

Preferred Stock

The Company's 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 the Company's common stock, issuable in one or more series. Upon issuance, the Company may 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

The Company's amended and restated certificate of incorporation authorizes the issuance of up to 190,000,000 shares of $0.001 par value common stock.

On August 8, 2025, the Company filed an automatic "shelf registration" statement on Form S-3 (the 2025 WKSI Shelf) as a "well-known seasoned issuer" (WKSI) as defined in Rule 405 under the Securities Act of 1933, as amended. The 2025 WKSI Shelf was declared effective upon filing and registers an unlimited amount of debt securities, equity securities, or other securities that the Company may issue and sell from time to time. The Company may offer and sell securities registered under the 2025 WKSI Shelf in one or more offerings, from time to time, depending on market conditions and its capital needs. The Company may also file additional registration statements in the future to maintain financing flexibility in support of its operations.

Share Repurchase Program and Treasury Stock

In August 2024, the Company's Board of Directors (the Board) authorized a share repurchase program (the Prior Share Repurchase Program) pursuant to which the Company could repurchase up to $100 million of its outstanding common stock. In September 2025, the Company announced the completion of the Prior Share Repurchase Program. Under the Prior Share Repurchase Program, the Company repurchased an aggregate of 3,502,334 shares of common stock at an average price of $28.55 per share.

In September 2025, the Board authorized and approved a new share repurchase program (the 2025 Share Repurchase Program) for up to $100 million of the currently outstanding shares of the Company's common stock. Under the 2025 Share Repurchase Program, the Company intends to repurchase shares through open market purchases, privately-negotiated transactions, or other methods in accordance with applicable federal securities laws, including Rule 10b-18 of the Exchange Act. The 2025 Share Repurchase Program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate the Company to acquire any particular amount of its common stock.

In March 2026, the Board authorized and approved an increase to the 2025 Share Repurchase Program from $100 million to $300 million. For the three months ended September 30, 2026, the Company repurchased 2,023,452 shares of common stock at an average price of $49.43 per share. As of September 30, 2026, the Company had repurchased approximately $200 million of common stock under the 2025 Share Repurchase Program at an average price of $37.37 per share.

As of September 30, 2026, 8,894,998 shares of common stock are being held in Treasury, at a cost of approximately $300.2 million, representing the fair market value on the date the shares were surrendered to the Company, mainly as part of the Prior Share Repurchase Program and the 2025 Share Repurchase Program.

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, 2026, 2,976,163 shares of restricted stock and 1,838,656 options were outstanding, and no additional shares were available to be issued under the 2012 Incentive Plan.

The TG Therapeutics, Inc. 2022 Incentive Plan (the 2022 Incentive Plan) was approved by stockholders in June 2022 with 17,000,000 shares available to be issued, and was amended to increase the shares available to be issued from 17,000,000 to 22,000,000 in June 2025 (the 2022 Incentive Plan Amendment). As of September 30, 2026, 8,072,886 shares of restricted stock and 2,185,500 options were outstanding, and 41,625 Stock Tracking Units (STUs) were reserved, leaving up to an additional 5,698,702 shares available to be issued under the 2022 Incentive Plan. The 2022 Incentive Plan is currently the Company's only active incentive plan. The Company's equity incentive plan includes both equity and liability-classified awards granted to employees and directors.

Restricted Stock

The following table summarizes the activity for restricted stock for the nine months ended September 30, 2026 and 2025:

	Restricted Stock	
	September 30, 2026	**September 30, 2025**
Restricted stock awards outstanding, beginning of year	12,011,881	11,843,586
Changes during the year:		
Granted	1,047,977	2,734,646
Vested	(1,872,654)	(1,810,349)
Expired or Forfeited	(138,155)	(236,279)
Restricted stock awards outstanding, end of period	11,049,049	12,531,604

These unvested shares are included in the Company's common shares issued and outstanding as reported on the condensed consolidated balance sheet.

Total stock-based compensation expense related to restricted stock grants was $11.7 million and $17.5 million for the three months ended September 30, 2026 and 2025, respectively, net of $0.5 million of expense capitalized into inventory during both periods. Total stock-based compensation expense related to restricted stock grants was $37.8 million and $48.0 million for the nine months ended September 30, 2026 and 2025, respectively, net of $1.7 million and $2.5 million of expense capitalized into inventory during the respective periods.

As of September 30, 2026, the Company had approximately $26.0 million of total unrecognized compensation expense related to unvested time-based restricted stock, expected to be recognized over a weighted-average period of 2.3 years.

Milestone-based noncash compensation expense will be recognized if and when achievement of the related milestone becomes probable. Awards with market conditions are valued using advanced option-pricing models, such as a Monte Carlo simulation, with the effect of the market condition reflected in the grant-date fair value. Compensation expense for awards with market conditions is recognized over the requisite service period determined by the grant-date valuation, regardless of whether the market condition is ultimately satisfied.

As of September 30, 2026, the Company had approximately $19.8 million of total unrecognized compensation expense related to unvested milestone-based restricted stock. Of this amount, $1.6 million is expected to be recognized over a weighted-average period of 0.5 years, while the remaining $18.2 million will be recognized only if and when achievement of the applicable milestones becomes probable. As of September 30, 2026, the Company had approximately $42.9 million related to restricted stock with market conditions, expected to be recognized over a weighted-average period of 2.5 years.

Stock Tracking Units (STUs)

The Company grants stock tracking units (STUs), which are equity-linked compensation awards granted under the TG Therapeutics, Inc. 2022 Incentive Plan. Each STU represents the right to receive the value of one share of the Company's common stock, either in cash or, for certain awards, in shares of stock. STUs may be either time-based awards or performance-based awards.

STUs are accounted for as liability awards and are remeasured at fair value at each reporting date, with changes in fair value recognized as stock-based compensation expense in the condensed consolidated statements of operations. The fair value of STUs is based on the closing price of the Company's common stock at each reporting date.

Compensation expense for STUs is recognized over the requisite service period. For STUs with performance conditions, expense is recognized when it is probable that the performance condition will be achieved. The related liability is recorded within accrued compensation and is adjusted each reporting period until settlement.

As of September 30, 2026, the Company had approximately 1,972,380 STUs outstanding. Stock-based compensation expense related to STUs was $12.9 million for the three months ended September 30, 2026, net of $0.6 million of expense capitalized into inventory. Stock-based compensation expense related to STUs was $34.3 million for the nine months ended September 30, 2026, net of $1.5 million of expense capitalized into inventory. The expense recognized during the three and nine months ended September 30, 2026 includes approximately $0.5 million and $9.1 million, respectively, attributable to the remeasurement of outstanding STUs to fair value based on the increase in the Company's closing stock price during the period. As of September 30, 2026, the Company had approximately $74.2 million of unrecognized compensation expense related to unvested STUs, expected to be recognized over a weighted-average period of 3.4 years.

Stock Options:

The following table summarizes the activity for stock options for the nine months ended September 30, 2026 and 2025:

	Stock Options	
	September 30, 2026	**September 30, 2025**
Stock options outstanding, beginning of year	4,204,816	4,470,216
Changes during the year:		
Granted	—	—
Exercised	(180,660)	(51,650)
Expired or Forfeited	—	(56,250)
Stock options outstanding, end of period	4,024,156	4,362,316

Total stock-based compensation expense associated with stock options was approximately $0.0 million and $0.2 million during the three months ended September 30, 2026 and 2025, respectively. Total stock-based compensation expense associated with stock options was approximately $0.4 million and $1.0 million during the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, there was no remaining unrecognized stock-based compensation expense related to unvested time-based stock options. As of September 30, 2026, stock options outstanding include options granted to both employees and non-employees, which are both time-based and milestone-based. Stock-based compensation for milestone-based options will be recorded if and when a milestone becomes probable.

Warrants

In September 2026, Hercules Capital, Inc. (Hercules) exercised its remaining warrants to purchase 115,042 and 50,172 shares of the Company's common stock at exercise prices of $17.95 and $14.70 per share, respectively. The warrants were issued in connection with the Company's prior loan agreement with Hercules, which has been repaid and terminated. The warrants were exercised on a cashless basis pursuant to the net exercise provisions of the warrant agreements, using a fair value of $55.29 per share and resulting in 114,525 net shares of the Company's common stock issuable to Hercules. As of September 30, 2026, no warrants remain outstanding.

NOTE 7 - LOAN PAYABLE

On August 2, 2024 (the Closing Date), the Company entered into a term loan facility of $250 million (the Initial Term Loan) with Blue Owl Capital Corporation, as administrative agent (the Administrative Agent), HealthCare Royalty (HCR) and Blue Owl Capital under the Financing Agreement (as defined below) to repay all outstanding principal and accrued interest and fees under our prior loan agreement with Hercules.

The Initial Term Loan is governed by a financing agreement (the Financing Agreement), which provides for (i) a single draw of the Initial Term Loan, which was funded on August 2, 2024, and (ii) an uncommitted additional facility in an aggregate principal amount of up to $100 million. The Initial Term Loan will mature on August 2, 2029 (the Term Loan Maturity Date). The Initial Term Loan accrues interest at a per annum rate of interest equal to an applicable margin plus, at the Company's option, either (a) a base rate determined by reference to the highest of (1) the prime rate published by The Wall Street Journal, (2) the federal funds effective rate plus 0.50% and (3) Term SOFR (as defined in the Financing Agreement), plus 1.00%.

On March 18, 2026 (the 2026 Closing Date), the Company entered into a First Amendment to the Financing Agreement (the First Amendment) to repay in full the Initial Term Loan and enter into a new term loan facility of $750 million (the 2026 Term Loan) with Blue Owl Capital. The 2026 Term Loan will mature on March 18, 2031 (the 2026 Term Loan Maturity Date). The 2026 Term Loan accrues interest at a per annum rate equal to an applicable margin plus (a) a base rate determined by reference to the highest of (1) the prime rate published by The Wall Street Journal, (2) the federal funds effective rate plus 0.50%, (3) Term SOFR plus 1.00% and (4) 2.00% or (b) Term SOFR, which shall be no less than 1.00%. The applicable margin is determined on a quarterly basis by reference to a pricing grid based on the Total Net Leverage Ratio (as defined in the First Amendment) for the most recently completed four consecutive fiscal quarters. The pricing grid commences at 4.75% for SOFR borrowings and 3.75% for base rate borrowings and is subject to a 25 basis point step-down upon achievement of a specified leverage threshold.

The 2026 Term Loan requires scheduled quarterly amortization payments commencing with the fiscal quarter ending March 31, 2030, in an amount equal to $37.5 million, with the balance due and payable on the 2026 Term Loan Maturity Date; provided that such amortization payments may be deferred upon the achievement of a Total Net Leverage Ratio that is less than or equal to an agreed threshold.

The 2026 Term Loan is secured by a lien on substantially all of the assets of the Company and certain subsidiaries of the Company as guarantors and contains customary covenants and representations. As of September 30, 2026, the Company was in compliance with all financial covenants.

The events of default under the Financing Agreement are customary for financings of this type. If an event of default occurs, Blue Owl Capital is entitled to take enforcement action, including acceleration of amounts due under the Financing Agreement. In connection with the 2026 Term Loan, the Company incurred additional third-party fees, which were capitalized as debt issuance costs and are being amortized over the term of the loan.

The Company evaluated the refinancing of the Initial Term Loan in connection with the First Amendment under ASC 470-50, Debt – Modifications and Extinguishments. The Company determined that the First Amendment represents a refinancing transaction resulting in extinguishment accounting for the Initial Term Loan held by Blue Owl Capital and HCR, which was repaid in full, including applicable prepayment premiums and accrued interest. As a result, the Company recorded a loss on extinguishment of debt of approximately $9.2 million in the Company's statement of operations for the nine months ended September 30, 2026, representing the write-off of a portion of unamortized debt issuance costs, unamortized debt discount costs, and the prepayment premiums associated with the extinguished portion.

The Company incurred total financing and upfront costs of $4.9 million related to the 2026 Term Loan, which are recorded as debt issuance costs and debt discount costs and as an offset to loan payable on the Company's consolidated balance sheet. The debt issuance and debt discount costs are being amortized over the term of the debt using the straight-line method, and will be included in interest expense in the Company's condensed consolidated statements of operations. Amortization of debt issuance and debt discount costs was $0.8 million for the nine months ended September 30, 2026, and $0.9 million for the nine months ended September 30, 2025. At September 30, 2026, the remaining unamortized balance of debt issuance and discount costs was approximately $4.4 million.

The loan payable balance of the Initial Term Loan as of September 30, 2026, and December 31, 2025 is as follows:

	The Initial Term Loan	
(in thousands)	September 30, 2026	December 31, 2025
Loan payable	$ 250,000	$ 250,000
Add: Accreted Liability of final payment fee	—	—
	250,000	250,000
Less: unamortized debt issuance and debt discount costs	—	(4,355)
	250,000	245,645
Less: principal payments	(250,000)	—
Total loan payable	—	245,645
Less: current portion	—	—
Loan payable non-current	$ —	$ 245,645

The loan payable balance of the 2026 Term Loan as of September 30, 2026, is as follows:

	2026 Term Loan
(in thousands)	September 30, 2026
Loan payable	$ 750,000
Add: Accreted Liability of final payment fee	—
	750,000
Less: unamortized debt issuance and debt discount costs	(4,366)
	745,634
Less: principal payments	—
Total loan payable	745,634
Less: current portion	—
Loan payable non-current	$ 745,634

NOTE 8 - LEASES

In October 2014, the Company entered into an agreement (the Office Agreement) with Fortress Biotech, Inc. (FBIO) to occupy a portion of the approximately 24,000 square feet of office space in New York City leased by FBIO. The Office Agreement requires the Company to pay its proportionate share of rent and other costs associated with the underlying lease. In connection with the Office Agreement, the Company pledged $1.3 million to secure a line of credit as a security deposit, which is recorded as restricted cash in the accompanying condensed consolidated balance sheets. The Office Agreement is being treated as a related party transaction.

In February 2026, FBIO entered into a sublease agreement with a third party for substantially all of the office space subject to the Office Agreement. Concurrently, the Company and FBIO amended the Office Agreement to reduce the Company's share of rent and other costs for the remaining lease term. The Company evaluated the amendment and determined that it represents a lease modification under ASC 842, Leases. As a result of the modification, the Company remeasured its operating lease liability with a corresponding adjustment to the related right-of-use asset. The remeasurement resulted in a reduction of both the operating lease liability and right-of-use asset of approximately $1.1 million as of September 30, 2026.

The Company remains obligated under the Office Agreement for its proportionate share of rent and related costs through the expiration of the lease term and may be required to fund its share of any shortfall between the head lease obligations and sublease income. The modification is expected to reduce the Company's lease expense prospectively.

In March 2026, the Company finalized an approximately five-year lease for office space in New York City (the Gansevoort Lease). The Company estimates an average annual rental obligation of approximately $0.4 million under the Gansevoort Lease. The Company took possession of this space in March 2026, with rental payments beginning in July 2026.

In October 2021, the Company finalized a five-year lease for office space in North Carolina (the NC Lease). The Company estimates an average annual rental obligation of $0.2 million under the NC Lease. The Company took possession of this space in February 2022, with rental payments beginning in April 2022. The Company incurred rental expense of $0.2 million for the nine months ended September 30, 2026. In May 2026, the Company amended the NC Lease to extend the lease term from the original expiration date of April 30, 2027 to June 30, 2032. The Company evaluated the amendment and determined that it represents a lease modification under ASC 842, Leases. As a result of the modification, the Company remeasured its operating lease liability with a corresponding adjustment to the related right-of-use asset. The remeasurement resulted in a reduction of both the operating lease liability and right-of-use asset of approximately $0.9 million as of September 30, 2026.

The present values of the Company's lease liability and corresponding Right-of-Use (ROU) asset are $8.7 million and $6.8 million, respectively, as of September 30, 2026. The Company's leases have remaining lease terms of one to six years. One lease has a renewal option to extend the lease for an additional term of five years. The following components of lease expense are included in the condensed consolidated statements of operations for the three and nine months ended September 30, 2026 and 2025:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2026	2025	2026	2025
Operating lease cost	$ 333	$ 477	$ 1,335	$ 1,455
Net lease cost	$ 333	$ 477	$ 1,335	$ 1,455

As of September 30, 2026, the weighted-average remaining operating lease term was 5.2 years and the weighted-average discount rate for operating leases was 8.44%. Cash paid for amounts included in the measurement of operating lease liabilities during the nine months ended September 30, 2026 was $1.3 million. The balance sheet classification of lease liabilities was as follows:

(in thousands)	September 30, 2026	December 31, 2025
Liabilities		
Lease liability current portion	$ 1,844	$ 1,044
Lease liability non-current	6,895	7,021
Total lease liability	$ 8,739	$ 8,065

As of September 30, 2026, the maturities of lease liabilities were as follows:

(in thousands)	Operating leases
Remainder of 2026	$ 530
2027	1,965
2028	2,162
2029	2,200
2030	2,239
After 2031	1,706
Total lease payments	10,802
Less: interest	(2,063)
Present value of lease liabilities(*)	$ 8,739

(*) As the Company's leases do not provide an implicit rate, the Company uses its 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. The Company used the incremental borrowing rate of 10.25% on February 28, 2019, for operating leases that commenced prior to that date through December 31, 2021. The Company used an incremental borrowing rate of 5.65% for the NC lease. The Company used an incremental borrowing rate of 8.4% for the modified Office Agreement operating lease.

NOTE 9 - LICENSE AGREEMENTS

BRIUMVI (Ublituximab)

In January 2012, the Company entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the LFB License Agreement). Under the terms of the LFB License Agreement, the Company acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. From the inception of the LFB License Agreement, the Company incurred expenses of approximately $31.0 million related to the achievement of certain milestones under the LFB License Agreement. These expenses are included in other research and development expenses in the accompanying condensed consolidated statements of operations. No further milestone payments remain payable under the LFB License Agreement.

LFB Group is eligible to receive 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 fifteen years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party. During the three and nine months ended September 30, 2026, the Company recorded $25.1 million and $70.1 million, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of revenue. As of September 30, 2026, $25.1 million in royalties payable under the LFB License Agreement remains outstanding in accounts payable and accrued expenses.

Neuraxpharm Commercialization Agreement

In July 2023, the Company entered into the Commercialization Agreement with Neuraxpharm. The Company granted Neuraxpharm the exclusive right to commercialize BRIUMVI in certain territories outside the United States, Canada, and Mexico, the commercialization rights for which had been previously retained by the Company, and excluding certain Asian countries subject to previously existing partnerships. Under the terms of the Commercialization Agreement, the Company received a one-time, non-refundable payment of $140.0 million upon contract execution and a $12.5 million milestone payment upon the first key market commercial launch in the EU. The Company is eligible to receive up to an additional $482.5 million in milestone-based payments upon achievement of certain launch and commercial milestones. During the three months ended September 30, 2026 Neuraxpharm achieved €50 million of year-to-date BRIUMVI net sales entitling the Company to a one-time $10.0 million milestone payment which was recorded in license, milestone, royalty and other revenue. In addition, the Company will receive tiered double-digit royalties on net product sales up to 30%. During the three and nine months ended September 30, 2026, royalty revenue of $4.1 million and $10.4 million, respectively, was recognized.

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

The arrangement also provides Neuraxpharm with the right to make optional purchases of BRIUMVI (the Supply of Licensed Product). These optional purchases are accounted for as a separate contract when the right to purchase BRIUMVI is exercised. The consideration for optional purchases approximates a market-based price for BRIUMVI by Neuraxpharm in the Territory. The consideration received for optional purchases is generally received in advance of shipment and is recognized by the Company as deferred revenue until the related performance obligation is met. The performance obligation is met when control of the product passes to Neuraxpharm, at which time the optional purchases are recognized as a component of product revenue, net.

As of September 30, 2026, the Company had $33.2 million of deferred revenue related to optional purchases for which the performance obligation had not been met. This includes $12.1 million recorded in accounts receivable, net for consideration the Company has an unconditional right to receive from Neuraxpharm under the Commercialization Agreement. The Company reevaluates the consideration received, and performance obligations satisfied, at the end of each reporting period. Such reevaluations may result in a change to the amount of product revenue, net, recognized and deferred revenue.

The Commercialization Agreement also grants Neuraxpharm the right to certain development, innovation, or modifications considered a product improvement (each, a Product Improvement). To license a Product Improvement, Neuraxpharm must reimburse the Company for 25% of costs actually incurred through the opt-in date, and 25% of eligible costs incurred by or on behalf of the Company after that date for the related development activities.

During the three months ended September 30, 2026, Neuraxpharm opted in to a Product Improvement for a new BRIUMVI dosing regimen that consolidates the initial 150 mg Day 1 dose and the 450 mg Day 15 dose into a single 600 mg dose on Day 1 (the 600 mg Product Improvement). Neuraxpharm’s share of development costs through the opt-in date was $5.0 million, which was recorded in license, milestone, royalty and other revenue.

Azer-cel

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

Pursuant to the Precision License Agreement, the Company made an upfront payment to Precision of $7.5 million, consisting of (i) $5.25 million in cash and (ii) $2.25 million, as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock. In January 2025, the Company made a deferred payment of $2.5 million to Precision consisting of an equity investment in Precision's common stock at a 100% premium to the 30-day volume-weighted average price (the 30-day VWAP) prior to purchase. In February 2026, the Company achieved the Milestone Event 1 (as defined in the Precision License Agreement) and made a one-time payment to Precision equal to $7.5 million comprised of (i) $5.25 million in cash and (ii) $2.25 million (the Milestone 1 Stock Payment), as an equity investment, for the purchase of 201,504 shares of Precision's common stock calculated by dividing the Deferred Precision Stock Payment by 200% of the weighted average share price of the Precision common stock for the thirty (30) trading days preceding the payment date.

Precision will be eligible to receive up to $286 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity, and a period of ten years following the first commercial sale of the licensed product in such country. As of September 30, 2026, none of the remaining near-term clinical milestones have been achieved.

MaxCyte

On February 10, 2025, the Company entered into the Strategic Platform License Agreement with MaxCyte, Inc. (MaxCyte), which granted a non-exclusive, non-transferable license for the Company to use MaxCyte's cell loading technology (licensed technology) to develop and commercialize products for the treatment of autoimmune and other non-oncology diseases and conditions, including azer-cel, licensed by the Company from Precision in January 2024.

MaxCyte is eligible to receive royalty payments on net sales of approved products developed with the licensed technology at a royalty rate in the low-single digits. Upon the achievement of the first dosing of a human subject in a pivotal trial for a product developed with the licensed technology the Company will make a $1.0 million payment to MaxCyte. MaxCyte is also eligible to receive up to $13.0 million in additional milestone payments based on the achievement of certain regulatory and marketing approvals. The Company is required to pay an annual licensing fee of approximately $0.2 million for access to the licensed technology.

The Strategic Platform License Agreement expires on the ten-year anniversary unless the Company achieves at least one of the milestone events prior to that date. The Company has the option, at its sole discretion, to extend the term of the Strategic Platform License Agreement beyond the initial ten years for successive renewal terms of five years each, as long as all applicable licensing fees and milestone payments are paid timely and the Company provides MaxCyte at least ninety days' written notice prior to the expiration of the then-current term.

NOTE 10 - INCOME TAXES

For the nine months ended September 30, 2026 and 2025, the Company recorded income tax expense of $21.4 million and income tax benefit of $361.8 million, respectively. The effective tax rates for the nine months ended September 30, 2026 and 2025 were 20.5% and (580.8)%, respectively. For the nine months ended September 30, 2026, the effective tax rate differs from the federal statutory rate primarily due to state income taxes, research and development tax credit, and stock-based compensation. For the nine months ended September 30, 2025, the effective tax rate differs from the federal statutory rate primarily due to a change in deferred tax asset valuation allowance.

For the three months ended September 30, 2026 and 2025, the Company recorded income tax expense of $18.4 million and income tax benefit of $365.0 million, respectively. The effective tax rates for the three months ended September 30, 2026 and 2025 were 24.9% and (1,408.7)%, respectively. For the three months ended September 30, 2026, the effective tax rate differs from the federal statutory rate primarily due to state income taxes, research and development tax credit, and stock-based compensation. For the three months ended September 30, 2025, the effective tax rate differs from the federal statutory rate primarily due to a change in deferred tax asset valuation allowance.

The Company is subject to income taxes in the U.S. and various state jurisdictions. Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against its net deferred tax assets. The Company monitors the realizability of its deferred tax assets at each reporting period. In completing the Company's assessment of realizability of its deferred tax assets, the Company considers, among other things: its history of income (loss) measured at pre-tax income (loss) adjusted for permanent book-tax differences on a jurisdictional basis; volatility in actual earnings; and the impacts of the timing of reversals of existing temporary differences. The Company also relies on its assessment of the Company's projected future results of business operations, including uncertainty in future operating results, variable macroeconomic conditions, and changes in business that may affect the existence and magnitude of future taxable income. The Company's valuation allowance assessment is based on its best estimate of future results considering all available information.

As of September 30, 2025, based on the relevant weight of positive and negative evidence, including improved and sustained profitability trends as well as consideration of the Company's expected future taxable earnings, the Company concluded that it is more likely than not that its U.S. federal and certain state deferred tax assets are realizable. As such, the Company released $371.7 million of its valuation allowance associated with the U.S. federal and state deferred tax assets, except for those related to certain state net operating loss carryforwards. The Company continues to maintain a full or partial valuation allowance against certain state attributes as of September 30, 2026, because the Company concluded it is not more likely than not to be realized, as the Company expects certain state attribute generation in future years to exceed its ability to use these deferred tax assets.

The Company's provision for income taxes for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items, if any, that are taken into account in the relevant period. Each quarter, the Company updates its estimate of the annual effective tax rate, and if the Company's estimated tax rate changes, it makes a cumulative adjustment.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has completed a study to assess whether an "ownership change" has occurred through December 31, 2023 as defined in Section 382. Based on the analysis, the Company experienced an ownership change in November 2012. The Company estimates the base Section 382 annual limitation regarding the Company's November 2012 ownership change to be immaterial. Future changes in the Company's stock ownership, which may be outside of its control, may trigger an additional "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an "ownership change" has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to us.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company contracts with various third parties to conduct certain activities including clinical operations and contract manufacturing, and for the clinical and commercial supply of BRIUMVI. Certain contracts contain non-cancelable features or require the Company to make binding forecasts for future purchases. As of September 30, 2026, the Company had aggregate non-cancelable purchase commitments of $219.8 million, of which $105.7 million and $114.1 million are expected to be incurred in the years 2027 and 2028, respectively. These amounts do not represent the Company's entire anticipated purchase requirements, as the amounts of such obligations will ultimately be dependent on the timing of future orders and the terms of the existing and future agreements, which cannot be reasonably estimated at this time.

Loan Payable

See Note 7 – Loan Payable for a detailed description of the Company's loan agreement.

Leases

See Note 8 – Leases for a detailed description of the Company's lease arrangements in New York and North Carolina.

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

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

You should read the following discussion and analysis in conjunction with the 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, 2025.

OVERVIEW

TG Therapeutics is a fully integrated, commercial-stage biotechnology company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline, TG Therapeutics has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI (ublituximab-xiiy) to treat adult patients with relapsing forms of multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval from several regulatory agencies outside of the U.S. for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

RECENT EVENTS

Data Presentations at the 10th Joint ACTRIMS-ECTRIMS Meeting

In October 2026, we presented several data sets at MSToronto2026, the 10th Joint ACTRIMS-ECTRIMS Meeting including:

Azer-cel in Primary Progressive Multiple Sclerosis: We presented results from our Phase 1 study evaluating azer-cel in patients with primary progressive multiple sclerosis (PPMS). Initial data demonstrated an encouraging safety profile in 26 participants, with no dose-limiting or high-grade CAR T-associated toxicities observed. Despite prior disease progression, 89% of evaluable participants had stable or improved disability scores at Day 90 and 88% at Day 180, with longer-term follow-up ongoing.

ENHANCE Phase 3 Trial in RMS: We presented results from the Phase 3 ENHANCE trial, a randomized, double-blind study evaluating a consolidated single infusion regimen for initiation of BRIUMVI in adults with RMS. The trial met its primary endpoint, demonstrating bioequivalent drug exposure between the currently approved BRIUMVI initiation infusion dosing regimen of 150 mg on Day 1 and 450 mg on Day 15 and a consolidated single 600 mg infusion on Day 1, eliminating the need for a Day 15 infusion. Infusion-related reactions were comparable between regimens, with no Grade 3 or higher reactions observed, supporting the potential for a simplified treatment initiation schedule.

Subcutaneous BRIUMVI in RMS: We presented the previously announced positive pharmacokinetic (PK), pharmacodynamic (PD), safety, and tolerability data from the Phase 1 clinical trial evaluating a subcutaneous formulation of ublituximab (the active agent in BRIUMVI). The PK and PD data from the Phase 1 clinical trial support quarterly subcutaneous BRIUMVI dosing regimen which is currently under evaluation in the fully enrolled Phase 3 trial. Topline data from the Phase 3 trial is expected around year-end 2026 or first quarter 2027.

Seven-Year BRIUMVI Data: We presented seven year follow-up data from the ULTIMATE I & II Phase 3 trials which supported the approval of BRIUMVI in relapsing MS. BRIUMVI demonstrated sustained efficacy with an annualized relapse rate (ARR) of 0.018 in the seventh year of treatment and 88.3% of continuously treated patients remaining free from 24-week confirmed disability progression. Patients receiving continuous BRIUMVI treatment experienced lower rates of disability progression than those who switched from teriflunomide, with a consistent long-term safety profile.

Phase 4 ENABLE Real-World Study: We presented updated data from 1,076 participants, 30% of whom switched from prior CD20 therapy, showed that 99.2% remained relapse-free during BRIUMVI treatment, with an ARR of 0.014. First-dose infusion-related reactions occurred in 18.8% of participants, and median subsequent infusion times of 63 minutes supported the one-hour infusion experience in clinical practice.

OUR PRODUCTS

We currently license worldwide development and commercial rights, subject to certain limited geographical restrictions, for all of our products under development. The following table summarizes select ongoing and planned clinical development programs for our lead drug candidates as of October 2026.

Clinical Drug Candidate: (molecular target)	**Disease**	**Stage/Status of Development**
BRIUMVI (anti-CD20 mAb)	RMS	APPROVED
BRIUMVI (simplified dosing) ENHANCE Trial	RMS	Positive topline Phase 3 data announced
BRIUMVI	Myasthenia Gravis (MG)	Phase 2 enrolling
BRIUMVI	Schizophrenia	Phase 2 enrolling
Ublituximab subcutaneous (anti-CD20 mAb)	RMS	Phase 3 completed enrollment
Azer-cel (anti-CD19)	Progressive Forms of Multiple Sclerosis (MS) and B-cell Disorders	Phase 1 enrolling

BRIUMVI (ublituximab-xiiy) Overview

Development of BRIUMVI in MS

BRIUMVI is an anti-CD20 monoclonal antibody that can be administered to adults with RMS in a one-hour infusion every 24 weeks, following the starting dose. BRIUMVI received approval from the FDA primarily based on results from the ULTIMATE I and ULTIMATE II Phase 3 trials. Each trial was an independent global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing the efficacy and safety/tolerability of BRIUMVI (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 adult subjects with RMS.

- In December 2020, we announced positive top-line results from the ULTIMATE I & II trials. Both studies met their primary endpoint of significantly reducing annualized relapse rate (ARR) over a 96-week period ($p<0.005$ in each study) with BRIUMVI demonstrating an ARR of <0.10 in each of the studies. Relative reductions of approximately 60% and 50% in ARR over teriflunomide were observed in ULTIMATE I & II, respectively. Key secondary MRI endpoints were also met.
- On August 22, 2022, the full results from the ULTIMATE I & II trials were published in the New England Journal of Medicine.
- On December 28, 2022, we announced the FDA approved BRIUMVI for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- On February 27, 2024, we announced the issuance of three additional patents by the United States Patent and Trademark Office (USPTO) for BRIUMVI, which extended patent protection through 2042.
- In February 2026, five-year data from the ongoing open label extension (OLE) of the Phase 3 ULTIMATE I and II studies were published in JAMA Neurology.
- In May 2026, we announced the Phase 3 ENHANCE trial, a randomized, double-blind study evaluating a consolidated single infusion regimen for initiation of BRIUMVI in adults with RMS, met its primary endpoint, demonstrating bioequivalent drug exposure between the currently approved initiation infusion dosing regimen of 150 mg on Day 1 and 450 mg on Day 15 and a consolidated single 600 mg infusion on Day 1, eliminating the need for a Day 15 infusion.
- In June 2026, data from a post-hoc pooled analysis of the Phase 3 ULTIMATE I and II studies evaluating BRIUMVI in treatment-naïve adult patients with RMS was published in Frontiers in Immunology.

- In October 2026, results from a five-year matching-adjusted indirect comparison (MAIC) evaluating long-term relapse activity and disability progression outcomes with BRIUMVI® (ublituximab-xiiy) compared with ocrelizumab and ofatumumab in patients with relapsing multiple sclerosis (RMS) were published online in *Multiple Sclerosis and Related Disorders.*
- In October 2026, we presented the full results from the Phase 3 ENHANCE trial as well as seven year follow up data from the ULTIMATE I & II Phase 3 trials and an update from the Phase 4 ENABLE real world study at the 2026 joint ACTRIMS-ECTRIMS meeting.

Development of BRIUMVI Outside of MS

- In June 2026, we announced positive topline data from an ongoing Phase 1 clinical trial evaluating subcutaneous BRIUMVI in patients with AChR-antibody-positive MG and the initiation of a Phase 2 clinical trial evaluating BRIUMVI as a maintenance therapy following induction with efgartigimod in adult patients with MG. In the Phase 1, 11 patients were treated across cohorts that demonstrated subcutaneous BRIUMVI exposure at least equivalent to the approved IV BRIUMVI regimen. Key data highlights included:
    - Consistent reductions from baseline were observed across all MG outcome measures over time following treatment with subcutaneous BRIUMVI
    - At Week 24, 82% of patients achieved the Minimal Clinically Important Difference (MCID) in MG-ADL, defined as a decrease of ≥ 2, with a median time to MCID of 30 days
    - Overall, a mean 4.6 point improvement in MG-ADL was observed at Week 24
    - Subcutaneous BRIUMVI was generally well tolerated, with a safety profile appearing consistent with the established safety profile of IV BRIUMVI in patients with multiple sclerosis

- In July 2026, we announced the initiation of a Phase 2 clinical trial evaluating BRIUMVI in adults with treatment-resistant schizophrenia.

U.S. Commercialization of BRIUMVI in MS and Market Dynamics

BRIUMVI (ublituximab-xiiy), an anti-CD20 monoclonal antibody indicated for the treatment of adults with RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, was approved by the FDA in December 2022 and commercially launched in the United States in January 2023. BRIUMVI is administered as a one-hour, twice per year infusion following the starting dose. Since launch, our commercialization efforts have focused on expanding prescriber awareness, increasing penetration across infusion centers and neurology practices, securing payor coverage, and supporting patient access within a competitive RMS treatment landscape.

We believe BRIUMVI's clinical profile, including its one-hour infusion time and twice-annual dosing schedule, together with demonstrated efficacy and safety in pivotal trials and accumulating real-world experience, supports its positioning within the anti-CD20 therapeutic class. The anti-CD20 class represents a significant segment of the RMS market, reflecting physician familiarity with the mechanism of action and long-term treatment considerations. Our ability to expand adoption is dependent on continued execution across access and site-of-care pathways; however, uptake may be influenced by factors including established prescribing practices, patient switching dynamics, payor coverage and utilization management requirements, competitive contracting, site-of-care logistics, and evolving treatment guidelines.

The RMS market is highly competitive and includes numerous approved disease-modifying therapies with varying mechanisms of action, routes of administration, safety profiles, and dosing schedules. Competitive dynamics may be influenced by pricing and contracting strategies, payor utilization management practices, the introduction of new branded products or biosimilars, and broader healthcare system and macroeconomic conditions. Our ability to continue to grow BRIUMVI revenues will depend on sustained physician adoption, patient persistence and adherence, competitive differentiation within the anti-CD20 class, and continued access across commercial and government payors.

Our net product revenue is subject to gross-to-net adjustments, including mandatory government discounts and rebates, contractual rebates and chargebacks, trade discounts and allowances (including cash discounts), product returns, distribution fees, and patient support programs. These adjustments are influenced by payor and site of care mix, coverage determinations, contracting dynamics, and patient assistance utilization, and may fluctuate from period to period. As our commercial footprint expands and payor contracting strategies evolve, the magnitude and variability of these adjustments may change.

Ex-U.S. Commercialization of BRIUMVI

In June 2023, we announced that the EC granted approval of BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features. With this approval, the centralized marketing authorization is valid in all European Union (EU) member states, Iceland, Norway and Liechtenstein.

In August 2023, we announced an agreement with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), a leading European specialty pharmaceutical company focused on the treatment of CNS disorders, for the Ex-U.S. commercialization of BRIUMVI (Commercialization Agreement). Under the terms of the Commercialization Agreement, we received an upfront payment of $140 million, and $12.5 million upon launch in the first EU country in February 2024, and up to an additional $492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. The total deal is valued at up to $645 million in upfront and milestone payments. In addition, we will receive tiered double-digit royalties on net product sales up to 30%. In exchange, Neuraxpharm will have the exclusive right to commercialize BRIUMVI in territories outside the U.S., Canada and Mexico, which are retained by TG, and excluding certain Asian countries subject to previously existing partnerships.

In February 2024, we announced the commercial launch of BRIUMVI in the EU by Neuraxpharm, with BRIUMVI made available for commercial sale in Germany.

BRIUMVI is now approved in the EU, the United Kingdom, Switzerland, Australia, Kuwait, the United Arab Emirates, Israel, Saudi Arabia, Iceland and Brazil.

Development of Subcutaneous BRIUMVI (ublituximab)

In August 2024, we announced the initiation of a Phase 1 clinical trial evaluating subcutaneous ublituximab (the active ingredient in BRIUMVI), and sometimes otherwise referred to as “subcutaneous BRIUMVI” in patients with RMS.

In January 2025, we announced the first patients with MG had been enrolled in a clinical trial evaluating subcutaneous ublituximab.

In September 2025, we announced enrollment commenced in the Phase 3 pivotal program evaluating subcutaneous ublituximab. The Phase 3 pivotal program is a randomized, open label, parallel-group, multicenter study designed to evaluate the pharmacokinetics, pharmacodynamics, safety, radiological and clinical effects of subcutaneous ublituximab compared to IV BRIUMVI in adult participants with RMS. Participants were randomized into one of three arms: 8-week regimen of subcutaneous ublituximab, 12-week regimen of subcutaneous ublituximab or the currently approved IV BRIUMVI dosing schedule. The primary endpoint of the trial is to demonstrate non-inferior exposure of subcutaneous ublituximab compared to IV BRIUMVI as measured by area under the curve (AUC) at week 24. In April 2026, we announced the trial completed enrollment and topline data is expected around year-end 2026 or first quarter 2027.

In June 2026, we announced positive PK, PD, safety, and tolerability data from a Phase 1 clinical trial evaluating a high-concentration (400 mg/2 mL) subcutaneous ublituximab as compared to IV BRIUMVI. Over 100 patients had been treated in the trial, including more than 80 patients who received subcutaneous BRIUMVI across multiple dose levels (50 mg – 400 mg) in single and multiple dose cohorts. More than 225 subcutaneous injections of BRIUMVI were administered, of which over 75% were 400 mg (2 mL) injections. Key data highlights included:

Bioavailability/Pharmacokinetics (Drug Exposure):

- The overall concentration-time profile of subcutaneous BRIUMVI was consistent with expectations for a subcutaneous formulation, with a gradual absorption phase and lower peak concentrations relative to IV, and linear pharmacokinetics were observed over the entire dose range evaluated.
- Subcutaneous BRIUMVI demonstrated mean bioavailability of greater than 60% relative to IV administration, with the lower bound of the 95% confidence interval exceeding 55%.
- PK modeling and simulation informed by the Phase 1 bioavailability data support the conclusion that:
  - The quarterly subcutaneous dosing regimen that is being evaluated in the Phase 3 trial would achieve non-inferior total drug exposure over 24 weeks (AUC 0-Wk24) with an estimated geometric mean ratio (GMR) of 1.21 (with a lower bound of the 90% confidence interval at 1.15), as compared to IV BRIUMVI.
  - The every other month subcutaneous dosing regimen that is also being evaluated in the Phase 3 trial, would achieve non-inferior total drug exposure over 24 weeks (AUC 0-Wk24) with an estimated GMR of 1.58 (with a lower bound of the 90% confidence interval at 1.50), as compared to IV BRIUMVI.

- The lower bound of the 90% confidence intervals for both dosing regimens being evaluated in Phase 3 would exceed the threshold required to establish non-inferiority (>0.80), which is the primary endpoint of the ongoing Phase 3 trial.

Pharmacodynamics (Biologic Activity):
- Treatment with subcutaneous BRIUMVI resulted in B-cell depletion consistent with IV BRIUMVI, supporting the biological activity of the subcutaneous formulation.

Safety & Tolerability:
- Subcutaneous administration was generally well tolerated, with treatment-emergent adverse events (TEAEs) consistent with the known safety profile of IV BRIUMVI.
- Local injection-site reactions were infrequent, occurring in less than 5% of patients, and systemic injection-related reactions occurred in approximately 21% of patients. Local and systemic injection reactions were not dose dependent and predominantly occurred at the first injection and resolved in 100% of patients.
- No serious injection-site reactions and no new safety signals were observed.

In October 2026, the full results from the Phase 1 clinical trial evaluating a high-concentration (400 mg/2 mL) subcutaneous ublituximab as compared to IV BRIUMVI in participants with RMS were presented at the 2026 joint ACTRIMS-ECTRIMS meeting.

Azercabtagene Zapreleucel (azer-cel)

Azer-cel is an allogeneic (off-the-shelf) CD19-directed CAR T cell therapy under development by us for autoimmune diseases. Made from donor-derived T cells modified using a proprietary ARCUS genome editing technology, azer-cel recognizes the well characterized B-cell surface protein CD19, an important and validated target in several B-cell cancers and autoimmune diseases. Azer-cel is designed to minimize graft-versus-host disease, a significant complication associated with other donor-derived, cell-based therapies.

In August 2024, we announced FDA clearance of the IND for azer-cel for the treatment of progressive forms of MS.

In August 2025, we announced the first patient with progressive multiple sclerosis had been dosed with azer-cel in a Phase 1 trial. The Phase 1 trial has now been expanded to include patients with other B-cell disorders.

In October 2026, we presented the initial results from our Phase 1 study evaluating azer-cel in patients with PPMS at the 2026 joint ACTRIMS-ECTRIMS meeting. Initial data demonstrated an encouraging safety profile in 26 participants, with no dose-limiting or high-grade CAR T-associated toxicities observed. Despite prior disease progression, 89% of evaluable participants had stable or improved disability scores at Day 90 and 88% at Day 180, with longer-term follow-up ongoing.

For more information, please refer to our Annual Report on Form 10-K for the year ended December 31, 2025.

PIPELINE AND LIFECYCLE MANAGEMENT

In addition to the ongoing commercialization of BRIUMVI, we continue to invest in our commercial organization, infrastructure, and internal capabilities to support lifecycle management and potential expansion of the product's clinical and commercial profile. A key area of focus is the development of a subcutaneous formulation of ublituximab, which is being evaluated as a potential alternative route of administration that may offer increased convenience and flexibility for patients and healthcare providers. We are also exploring the use of BRIUMVI in autoimmune indications outside of MS and are advancing early-stage development activities for azer-cel in autoimmune diseases. These programs reflect our broader strategy to enhance the durability of our portfolio and expand future therapeutic opportunities.

Beyond BRIUMVI, we continue to evaluate potential in-licensing and acquisition opportunities. These opportunities may include earlier-stage programs, complementary products, proprietary technologies, or other therapeutic approaches that could enhance our pipeline and support long-term growth. The scope, timing, and level of any such investments will depend on a range of factors, including scientific and clinical data, manufacturing feasibility, regulatory considerations, commercial readiness, available resources, and overall strategic and financial priorities.

Financial Overview and Key Components of our Operating Results

Although we have recently achieved profitability, we have historically incurred substantial operating losses since our inception and may continue to experience fluctuations in operating results. Despite the commercialization of BRIUMVI and the potential future commercialization of other product candidates, there can be no assurance that we will maintain profitability on an ongoing basis.

For the nine months ended September 30, 2026, we generated revenue of $705.2 million and generated operating income and positive cash flows from operations. We will continue to invest in our research and development programs and in selling, general and administrative activities to support our commercialization efforts, while maintaining discipline around overall expense growth relative to revenue. Our operating results and cash flows have fluctuated in the past and may continue to vary significantly from period to period. We will need to generate substantial revenues to sustain profitability and positive cash flow over the long term.

As of September 30, 2026, our accumulated deficit was approximately $1.0 billion, and we had $556.7 million in cash and cash equivalents, and investment securities, excluding equity investments. Based on our current operating plan and results, we anticipate that our existing cash, cash equivalents, and investment securities, together with projected future revenues, will be sufficient to fund operations and meet our liquidity needs for more than twelve months after the date of filing of this Quarterly Report on Form 10-Q.

The actual level of cash required for operations will depend on numerous factors, including, among others, the scope of commercialization activities for BRIUMVI, the timing of collection of receivables from our customers on extended payment terms, the timing and design of clinical trials for our product candidates, and the costs associated with licensing or acquiring new product candidates. We do not currently expect to need to raise additional capital to fund our ongoing operations, but may from time to time seek additional financing to support strategic initiatives, including potential business development activities.

We expect our expenses to increase as we continue to grow and expand our clinical programs and pursue the potential commercialization of additional product candidates. We anticipate incurring significant research and development expenses related to these activities for the foreseeable future. The actual amount of cash needed to support these strategic initiatives will depend on many factors, including:

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

Cost of Revenue

Cost of revenue consists primarily of royalties owed to our licensing partner for BRIUMVI sales, materials and third-party manufacturing costs, freight, distribution and logistics expenses, and overhead costs associated with our supply chain. Cost of revenue may also include excess or obsolete inventory adjustments, abnormal manufacturing costs, unabsorbed overhead, and manufacturing variances.

In accordance with our policy to expense costs associated with the manufacture of our products prior to regulatory approval, a portion of the manufacturing costs incurred to produce BRIUMVI before its FDA approval in December 2022 were expensed to research and development. As a result, a portion of the BRIUMVI units recognized as revenue during the three months ended March 31, 2025 are not included in the cost of product revenue during those periods.

As commercialization continues and pre-approval inventory has been fully depleted, we expect cost of revenue and gross margin to normalize to levels that reflect current commercial manufacturing costs, royalty payments, and supply chain expenses. Period-over-period fluctuations in cost of revenue may continue to occur based on the nature of our ordinary course of business operations, including production scheduling, manufacturing, inventory management, the timing of overhead allocation and tariffs.

Research and Development (R&D) Expenses (Other)

Our other research and development expenses consist primarily of external clinical and manufacturing costs, personnel-related expenses, milestone and licensing payments, and overhead costs supporting development activities. We recognize R&D costs as incurred. These expenses include:

- *External development costs*, including amounts paid to contract research organizations (CROs), contract manufacturing organizations (CMOs), central laboratories, clinical trial sites, and other third-party service providers supporting our preclinical studies, clinical trials, process development and analytical testing;
- *Manufacturing and scale-up costs*, including costs associated with producing preclinical and clinical supply and performing process development and optimization activities. Prior to FDA approval of BRIUMVI, all manufacturing costs for ublituximab were expensed to R&D as incurred. Following approval, manufacturing costs related to commercial supply are capitalized as inventory;
- *Personnel and employee-related expenses*, including salaries, benefits, travel and share-based compensation for employees engaged in research, clinical development, medical, regulatory and manufacturing-support functions;
- *Milestone, licensing and collaboration expenses*, including upfront payments and milestone obligations incurred under in-license and collaboration agreements; and
- Facility and other overhead costs that support research and development activities.

S*elling, General, and Administrative (SG&A) Expenses (Other)*

Our other selling, general and administrative expenses consist primarily of expenses related to the commercialization of our approved products and the expenses required to maintain and support a growing commercial organization. These expenses include:

- *Commercial operations costs*, including salaries and related expenses, benefits, incentives, share-based compensation and travel for sales, marketing, and commercial development team, as well as promotional programs, marketing initiatives, medical affairs, and reimbursement support services related to BRIUMVI;
- *Corporate and administrative personnel costs*, including salaries, benefits, travel and share-based compensation for executive, finance, accounting, business development, legal, human resources, and other administrative functions;
- *Professional fees*, including legal services, patent-related costs associated with the protection and maintenance of our intellectual property and proprietary technologies, accounting and audit services, consulting services, external legal advisors, and other external advisors supporting our operations;
- *Corporate infrastructure and facilities costs*, including rent, utilities, insurance, information technology systems, and other overhead necessary for our day to day operations and to support our commercial and administrative activities;
- *Additional SG&A support functions*, such as medical affairs, legal activities, market access, reimbursement operations, and compliance.

RESULTS OF OPERATIONS

The following table summarizes the results of operations for the three months ended September 30, 2026 and 2025:

	Three months ended September 30,		
(in thousands)	2026	2025	Change
Product revenue, net	$ 240,043	$ 159,317	$ 80,726
License, milestone, royalty and other revenue	19,893	2,392	17,501
Total revenue	$ 259,936	$ 161,709	$ 98,227
Costs and expenses:			
Cost of revenue	42,079	28,093	13,986
Research and development:			
Stock-based compensation	7,550	5,335	2,215
Other research and development	43,740	35,543	8,197
Total research and development	51,290	40,878	10,412
Selling, general and administrative:			
Stock-based compensation	17,153	12,351	4,802
Other selling, general and administrative	63,515	51,022	12,493
Total selling, general and administrative	80,668	63,373	17,295
Total costs and expenses	174,037	132,344	41,693
Interest expense	15,819	6,721	9,098
Other income	(3,782)	(3,265)	(517)
Total other expense	12,037	3,456	8,581
Net income before taxes	$ 73,862	$ 25,909	$ 47,953
Income tax (expense) benefit	(18,399)	364,986	(383,385)
Net income	$ 55,463	$ 390,895	$ (335,432)

Product Revenue, Net. Product revenue, net was approximately $240.0 million for the three months ended September 30, 2026, compared to $159.3 million for the three months ended September 30, 2025. Product revenue, net for both the three months ended September 30, 2026 and 2025 consisted of net product sales of BRIUMVI in the United States of $232.6 million and $152.9 million, respectively. Also included in product revenue, net for the three months ended September 30, 2026 and 2025 is sales of BRIUMVI to our ex-U.S. licensing partner, Neuraxpharm, of $7.4 million and $6.4 million, respectively. The increase in product revenue, net is a result of greater market penetration of BRIUMVI in the United States and from commercial product sales supplied to Neuraxpharm under the Commercialization Agreement.

License, Milestone, Royalty and Other Revenue. License, milestone, royalty and other revenue was $19.9 million for the three months ended September 30, 2026 and $2.4 million for the three months ended September 30, 2025. License, milestone, royalty and other revenue for the three months ended September 30, 2026 is comprised of $4.1 million of royalty revenue recognized under the Commercialization Agreement with Neuraxpharm and $15.8 million of license, milestone, and other revenue, including $10.0 million related to a sales milestone achieved during the period, $5.0 million in license revenue, and $0.8 million for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement (see Note 2 – Revenue for more information).

Cost of Revenue. Cost of revenue for the three months ended September 30, 2026 was $42.1 million compared to approximately $28.1 million for the three months ended September 30, 2025. Cost of revenue for both periods consisted primarily of royalties owed to our licensing partner for BRIUMVI sales, as well as third-party manufacturing, distribution and overhead costs. The increase was primarily driven by growth in BRIUMVI U.S. sales volume and sales to our ex-U.S. licensing partner, Neuraxpharm, during the three months ended September 30, 2026. Gross margin on BRIUMVI U.S. net product revenue remained approximately 87% during the three months ended September 30, 2026. Total gross margin was approximately 84%, reflecting the impact of sales to Neuraxpharm and other revenue sources, which carry different margins than BRIUMVI U.S. net product revenue.

Stock-Based Compensation Expense (Research and Development). Stock-based compensation expense (research and development) related to equity incentive grants and liability-classified awards totaled $7.6 million for the three months ended September 30, 2026, as compared to $5.3 million during the comparable period ended September 30, 2025. The increase in stock-based compensation expense for the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, was primarily due to the mark-to-market impact on stock tracking units and an increase in headcount.

Other Research and Development Expense. Other research and development expense was $43.7 million for the three months ended September 30, 2026, as compared to $35.5 million during the three months ended September 30, 2025. The increase in research and development expense during the three months ended September 30, 2026 was primarily attributable to an increase in clinical trial related expenses pertaining to our clinical pipeline during the period ended September 30, 2026.

Stock-Based Compensation Expense (Selling, General and Administrative). Stock-based compensation expense (selling, general and administrative) related to equity incentive grants and liability-classified awards totaled $17.2 million for the three months ended September 30, 2026, as compared to $12.4 million during the comparable period ended September 30, 2025. The increase in stock-based compensation expense was primarily due to the mark-to-market impact on stock tracking units, and greater recognition of stock-based compensation expense for market-based awards during the three months ended September 30, 2026.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled $63.5 million for the three months ended September 30, 2026, as compared to $51.0 million during the comparable period ended September 30, 2025. The increase was primarily due to marketing and media spend, and personnel-related costs associated with the commercialization of BRIUMVI during the three months ended September 30, 2026.

Interest Expense. Interest expense totaled $15.8 million for the three months ended September 30, 2026, as compared to $6.7 million for the three months ended September 30, 2025. The increase is mainly due to increased interest expense pertaining to the First Amendment to the Financing Agreement with Blue Owl Capital during the three months ended September 30, 2026 (see Note 7 – Loan Payable for more information).

Other Income. Other income totaled $3.8 million for the three months ended September 30, 2026, as compared to $3.3 million during the comparable period ended September 30, 2025. The increase is mainly due to more income earned from investments during the three months ended September 30, 2026.

Income Tax (Expense) Benefit. Income tax expense totaled $18.4 million for the three months ended September 30, 2026, as compared to income tax benefit of $365.0 million during the comparable period ended September 30, 2025. The decrease was primarily due to the discrete release of our deferred tax asset valuation allowance during the quarter ended September 30, 2025.

The following table summarizes the results of operations for the nine months ended September 30, 2026 and 2025:

	Nine months ended September 30,		
(in thousands)	2026	2025	Change
Product revenue, net	$ 677,145	$ 417,815	$ 259,330
License, milestone, royalty and other revenue	28,044	5,898	22,146
Total revenue	$ 705,189	$ 423,713	$ 281,476
Costs and expenses:			
Cost of revenue	116,783	62,572	54,211
Research and development:			
Stock-based compensation	20,495	12,984	7,511
Other research and development	174,528	106,038	68,490
Total research and development	195,023	119,022	76,001
Selling, general and administrative:			
Stock-based compensation	52,033	36,035	15,998
Other selling, general and administrative	198,982	133,254	65,728
Total selling, general and administrative	251,015	169,289	81,726
Total costs and expenses	562,821	350,883	211,938
Interest expense	40,057	20,194	19,863
Loss on extinguishment of debt	9,153	—	9,153
Other income	(11,301)	(9,661)	(1,640)
Total other expense	37,909	10,533	27,376
Net income before taxes	$ 104,459	$ 62,297	$ 42,162
Income tax (expense) benefit	(21,438)	361,845	(383,283)
Net income	$ 83,021	$ 424,142	$ (341,121)

Product Revenue, Net. Product revenue, net was approximately $677.1 million for the nine months ended September 30, 2026, compared to $417.8 million for the nine months ended September 30, 2025. Product revenue, net for both the nine months ended September 30, 2026 and September 30, 2025 consisted of net product sales of BRIUMVI in the United States of $655.1 million and $411.4 million, respectively. Also included in product revenue, net for the nine months ended September 30, 2026 and 2025 is sales of BRIUMVI to our ex-U.S. licensing partner, Neuraxpharm, of $22.0 million and $6.4 million, respectively. The increase in product revenue, net is a result of greater market penetration of BRIUMVI in the United States and from commercial product sales supplied to Neuraxpharm under the Commercialization Agreement.

License, Milestone, Royalty and Other Revenue. License, milestone, royalty and other revenue was $28.0 million for the nine months ended September 30, 2026 and $5.9 million for the nine months ended September 30, 2025. License, milestone, royalty and other revenue for the nine months ended September 30, 2026 is comprised of $10.4 million of royalty revenue recognized under the Commercialization Agreement with Neuraxpharm, and $17.6 million of license, milestone, and other revenue, including $10.0 million related to a sales milestone achieved during the period, $5.0 million in license revenue, and $2.6 million for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement (see Note 2 – Revenue for more information).

Cost of Revenue. Cost of revenue for the nine months ended September 30, 2026 was $116.8 million compared to approximately $62.6 million for the nine months ended September 30, 2025. Cost of revenue for both periods consisted primarily of royalties owed to our licensing partner for BRIUMVI sales, as well as third-party manufacturing, distribution and overhead costs. The increase was primarily driven by growth in BRIUMVI U.S. sales volume and sales to our ex-U.S. licensing partner, Neuraxpharm, during the nine months ended September 30, 2026. Gross margin on BRIUMVI U.S. net product revenue remained approximately 87% during the nine months ended September 30, 2026. Total gross margin was approximately 83%, reflecting the impact of sales to Neuraxpharm and other revenue sources, which carry different margins than BRIUMVI U.S. net product revenue.

Stock-Based Compensation Expense (Research and Development). Stock-based compensation expense (research and development) related to equity incentive grants and liability-classified awards totaled $20.5 million for the nine months ended September 30, 2026, as compared to $13.0 million during the comparable period ended September 30, 2025. The increase in stock-based compensation expense was primarily due to the mark to market impact on stock tracking units, and an increase in headcount during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

Other Research and Development Expense. Other research and development expense was $174.5 million for the nine months ended September 30, 2026, as compared to $106.0 million during the nine months ended September 30, 2025. The increase in research and development expense during the nine months ended September 30, 2026 was primarily attributable to an increase in manufacturing expense in connection with our subcutaneous development work, and increased clinical trial related expenses pertaining to our clinical pipeline during the period ended September 30, 2026.

Stock-Based Compensation Expense (Selling, General and Administrative). Stock-based compensation expense (selling, general and administrative) related to equity incentive grants and liability-classified awards totaled $52.0 million for the nine months ended September 30, 2026, as compared to $36.0 million during the comparable period ended September 30, 2025. The increase in stock-based compensation expense was primarily due to the mark-to-market impact on stock tracking units, and greater recognition of stock-based compensation expense for market-based awards during the nine months ended September 30, 2026.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled $199.0 million for the nine months ended September 30, 2026, as compared to $133.3 million during the comparable period ended September 30, 2025. The increase was primarily due to marketing and media spend, and personnel-related costs associated with the commercialization of BRIUMVI during the nine months ended September 30, 2026.

Interest Expense. Interest expense totaled $40.1 million for the nine months ended September 30, 2026, as compared to $20.2 million for the nine months ended September 30, 2025. The increase is mainly due to increased interest expense pertaining to the First Amendment to the Financing Agreement with Blue Owl Capital during the nine months ended September 30, 2026 (see Note 7 – Loan Payable for more information).

Loss on extinguishment of debt. Loss on extinguishment of debt totaled $9.2 million for the nine months ended September 30, 2026 related to the write-off of unamortized deferred financing and debt discount costs, as well as prepayment fees associated with the Initial Term Loan with Blue Owl Capital, as compared to zero for the nine months ended September 30, 2025 (see Note 7 – Loan Payable for more information).

Other Income. Other income totaled $11.3 million for the nine months ended September 30, 2026, as compared to $9.7 million during the comparable period ended September 30, 2025. The increase is mainly due to more income earned from investments during the nine months ended September 30, 2026.

Income Tax (Expense) Benefit. Income tax expense totaled $21.4 million for the nine months ended September 30, 2026, as compared to income tax benefit of $361.8 million during the comparable period ended September 30, 2025. The decrease was primarily due to the discrete release of our deferred tax asset valuation allowance during the quarter ended September 30, 2025.

Material Cash Requirements and Contractual Obligations

Our material cash requirements primarily relate to the continued commercialization of BRIUMVI, including commercial operations, manufacturing and supply commitments, medical affairs activities, post-marketing requirements, and ongoing clinical development programs, as well as general and administrative expenses supporting our commercial-stage operations. Certain of these requirements arise from contractual commitments, while others are driven by our operating plan and the ordinary course of business.

We expect to fund these expenditures through existing cash, cash equivalents and investment securities, cash flows from BRIUMVI product sales, and, if needed, access to additional capital under the uncommitted portion of our term loan facility with Blue Owl Capital or other financing sources.

As of September 30, 2026, our contractual obligations consist primarily of purchase and supply commitments supporting the commercial and clinical manufacture of BRIUMVI. Certain of these agreements include non-cancelable provisions, minimum purchase requirements, or binding forecast commitments. We also maintain lease obligations for our office facilities in New York and North Carolina, which are expected to be funded through operating cash flows.

In accordance with our Financing Agreement with Blue Owl Capital, we are obligated to make interest and future principal payments.

We also enter into collaboration and license agreements that may require future milestone and royalty payments. Because these payments are contingent upon the achievement of specified events, they are not included in our contractual commitments but could become material in future periods.

Based on our current operating plan, financial resources, and projected results, we believe we have sufficient liquidity to fund operations and meet our material cash requirements for at least the next twelve months from the date of filing of this Quarterly Report on Form 10-Q. However, future capital requirements will depend on a number of factors, and additional financing may be required.

Discussion of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2026 and 2025:

	Nine months ended September 30,	
(in thousands)	**2026**	**2025**
Net cash provided by (used in) operating activities	$ 66,596	$ (44,432)
Net cash (used in) provided by investing activities	$ (7,504)	$ 29,437
Net cash provided by (used in) financing activities	$ 291,169	$ (90,787)

Net cash provided by operating activities for the nine months ended September 30, 2026 was $66.6 million as compared to net cash used in operating activities of $44.4 million for the nine months ended September 30, 2025, representing a $111.0 million improvement year over year. Net income in the prior-year period included a non-cash income tax benefit from the release of the valuation allowance on our deferred tax assets in the third quarter of 2025. Excluding the impact of deferred income taxes, the improvement in operating cash flow was primarily driven by favorable changes in operating assets and liabilities of $45.0 million, as well as an increase in stock-based compensation during the nine months ended September 30, 2026.

Net cash used in investing activities for the nine months ended September 30, 2026 was $7.5 million, as compared to $29.4 million provided by investing activities for the nine months ended September 30, 2025. The change in net cash used in investing activities was primarily due to decreased proceeds from maturities of held-to-maturity securities during the nine months ended September 30, 2026, partially offset by decreased investments in held-to-maturity securities during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

Net cash provided by financing activities for the nine months ended September 30, 2026 was approximately $291.2 million as compared to net cash used in financing activities of $90.8 million for the nine months ended September 30, 2025. The increase in net cash provided by financing activities during the nine months ended September 30, 2026 was mainly due to the proceeds from the 2026 Term Loan, net of financing costs paid, partially offset by the repurchase of stock under our 2025 share repurchase program.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES 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 Annual Report on Form 10-K for the year ended December 31, 2025, and refer to Note 1 - Organization and Summary of Significant Accounting Policies 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, deferred tax asset valuation allowance, and cost of revenue. Of these policies, the following are considered critical to an understanding of our condensed consolidated financial statements as they require the application of the most difficult, subjective and complex judgments: revenue recognition and stock-based compensation expenses. Refer to Note 2 – Revenue and Note 6 – Stock-Based Compensation respectively, in this Quarterly Report on Form 10-Q for more information.

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, 2025.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, 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, 2026, 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, 2026 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 on Form 10-Q 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. Investors should also refer to the other information contained or incorporated by reference in this Quarterly Report on Form 10-Q, including our financial statements and related notes, and our other filings from time to time with the SEC.

Risks Related to Commercialization

If BRIUMVI or any product candidate for which we obtain marketing approval from the United States (U.S.) Food and Drug Administration (FDA) or any comparable regulatory authority outside of the U.S. does not achieve or maintain broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from product sales will be limited.

We currently have one marketed product, BRIUMVI, which received approval from the FDA in December 2022, for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, as well as approval by several regulatory authorities outside of the U.S. for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features.

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

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

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

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

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

Regulatory approvals for our product or any of our product candidates may be subject to conditions and limitations on the approved indicated uses for which the product may be marketed or contain requirements or commitments for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance and pharmacovigilance to monitor the safety and efficacy of the approved product candidate. For example, with respect to the FDA's approval of BRIUMVI for RMS, the approval is subject to certain post-marketing requirements and commitments, including long-term safety studies, as well as studies to evaluate the effects of BRIUMVI in pregnant women and pediatric populations, among others. Similar post-approval studies are required by other regulatory authorities outside of the U.S. These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market BRIUMVI, or negatively impact its overall clinical profile. There are currently ongoing clinical studies evaluating BRIUMVI in patients with RMS, but the ultimate outcome of these and other studies remains uncertain.

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

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

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

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

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

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

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

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

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

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and commercialization resources. Large pharmaceutical companies have extensive experience commercializing products and may have significant existing relationships with customers and more resources available to them to promote their products. Many are active in the same disease areas that we are, including within the neurological and immunological fields, some in direct competition with us. We may also compete with these organizations to recruit commercial and other key personnel, as well as study subjects for clinical trials. 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), direct-to-consumer advertising and non-promotional communications (certain educational and scientific exchange), and with regard to potential competitor actions under federal law (such as the Lanham Act) and congruous state law, which protect businesses against the unfair competition of misleading advertising or labeling.

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

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

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

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

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

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

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

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.

In addition, legislative and regulatory proposals in the United States have included “most favored nation” (MFN) or international reference pricing models that would tie reimbursement or net prices for certain drugs to the lowest price available in other countries. Adoption or expansion of MFN or similar reference pricing policies could result in downward pressure on U.S. pricing if BRIUMVI or any of our future products are sold at lower net prices in ex-U.S. markets. Because we have partnered the rights to commercialize BRIUMVI in territories outside of the U.S. and do not control pricing, reimbursement negotiations or commercial strategy in those territories, we may have limited ability to influence ex-U.S. pricing decisions that could be used as reference points under MFN or similar frameworks. As a result, pricing determinations made by our collaboration partner in Europe, including in response to local market access dynamics or governmental requirements, could adversely affect the reimbursement or net price realized for BRIUMVI in the U.S. or other markets, which could have a material adverse effect on our revenues and results of operations.

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

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

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

Additional factors that may inhibit our efforts to support the ongoing commercialization of BRIUMVI and our product candidates on our own, or through partnership, and generate product revenues include:

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

We have entered into a Commercialization Agreement for the sale of BRIUMVI in certain territories outside the U.S., Canada and Mexico, the commercialization rights for which had been previously retained by the Company, which excludes certain countries in Asia subject to previously existing partnerships. We may enter into additional agreements in the future to facilitate commercialization of BRIUMVI and/or future products that receive approval in markets outside the U.S. through partnerships. In February 2024, BRIUMVI was first made available in the European market by Neuraxpharm in Germany and is now commercially available in several other jurisdictions outside of the U.S. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any products or product candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product or product candidates effectively. If we decide to build and maintain a commercial infrastructure on our own in markets outside of the U.S., we expect to incur significant expenses, which could have a negative impact on our cash resources. 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 could be materially adversely affected.

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

- decreased demand for any products that we may commercialize;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation, including the risk that any individuals who may face such related litigation may in turn seek to recover from us;

- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products or product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive and difficult to obtain and maintain. 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.

Any contracts that we enter into with government entities may involve future funding and compliance risks.

Any contracts that we enter into with government entities may involve future funding and compliance risks. Such contracts with government entities are generally subject to risks such as lack of funding and compliance with unique requirements. For example, government contract purchase obligations are typically subject to the availability of funding, which may be eliminated or reduced. In the current U.S. political environment, there is significant uncertainty with respect to legislation, regulation and policy throughout the government with particular implications for companies that rely on government contracts. For a discussion on tariffs and changes to government regulations, including the BIOSECURE Act and related risks, see "Risk Factors – Risks Related to Our Business Organization and Governance, Strategy, Employees and Growth Management – Unfavorable global economic conditions and changes in government regulations could adversely affect our business, financial condition or results of operations." Policy changes, shifts in international and trade relations, tariffs, budget uncertainty, shifting funding priorities, U.S. government shutdowns or the need to operate under continuing resolutions, the failure of the U.S. government to manage debt, the failure of the U.S. government to approve budgets, and/or other disruptions to federal government operations could result in contract terminations, delays in contract awards, reduction in contract scope, the failure to exercise contract options, the cancellation of planned procurements and fewer new business opportunities, all of which could have a material and adverse effect on our business, financial condition, and results of operations. In addition, the future volume of products or services purchased by a government customer is often uncertain. Any of our government contracts might not be renewed or might be terminated for convenience with little prior notice. Contracts with government entities are typically subject to procurement laws that include socio-economic impacts, employment practices, environmental protection, recordkeeping and accounting obligations, and other requirements. These contractual and legal requirements could complicate our business and increase our compliance burden. The occurrence of any of these risks could harm our reputation and might have a materially adverse impact on our business operations, financial position and/or results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of losses and our ability to maintain profitability in the future remains uncertain. We expect to incur significant expenses for the foreseeable future as we commercialize BRIUMVI and advance our product candidates through clinical trials, seek regulatory approvals and pursue commercialization.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in January 2012 and currently have one marketed product, BRIUMVI, which received approval from the FDA in December 2022. We have focused our efforts and financial resources on clinical trials, manufacturing of our products and product candidates, establishing a commercial infrastructure and preparing to support a commercial product. To date, we have financed our operations primarily through public offerings of our common stock and debt financing, and product revenues generated from BRIUMVI. We expect to continue to incur significant research and development expenses, as well as significant commercialization and outsourced manufacturing expenses as we continue to commercialize BRIUMVI and advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses, or for how long we may continue to experience profitability. We may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to maintain profitability depends upon our ability to generate substantial revenue. Our prior losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital should we be unable to maintain profitability in future periods.

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

- successfully complete clinical trials that meet their clinical endpoints;

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

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

We may seek additional capital to support our business, strategic initiatives or other corporate purposes, and if adequate financing is not available when needed, our business and growth prospects could be adversely affected.

The development and commercialization of innovative therapies is capital intensive. We expect to continue to invest substantially in the commercialization and lifecycle management of BRIUMVI, including the generation of additional clinical data to support its long-term commercial adoption and potential expansion into additional indications and formulations. We also expect to continue investing in the advancement of our clinical pipeline, including programs evaluating subcutaneous (SubQ) ublituximab, optimization of intravenous BRIUMVI for patients with RMS, the evaluation of BRIUMVI in additional autoimmune diseases, azer-cel for the treatment of primary progressive multiple sclerosis, and other current or future development programs. In addition, we expect to continue to incur significant research and development, manufacturing, commercialization and general and administrative expenses as we execute our business strategy.

Although we believe that our existing cash, cash equivalents, investments, anticipated revenues from BRIUMVI and other available sources of capital will be sufficient to fund our currently planned operations for the foreseeable future, our future capital requirements will depend on many factors, including:

- the commercial performance of BRIUMVI and any future approved products;
- the timing, scope, costs and results of our research and development programs and clinical trials;
- the costs of manufacturing clinical and commercial product supply;
- the timing and costs associated with obtaining and maintaining regulatory approvals and satisfying post-marketing requirements;
- the costs of expanding our commercial infrastructure and supporting future product launches;
- our ability to enter into and timing of strategic collaborations, licensing arrangements and/or other business development transactions;
- the costs of protecting, maintaining and enforcing our intellectual property rights and defending against third-party claims; and
- opportunities to acquire, license or invest in additional technologies, product candidates or businesses.

We may from time to time opportunistically seek additional capital through equity offerings, debt financings, strategic collaborations, licensing arrangements or other financing transactions to support our business, pursue strategic opportunities, strengthen our balance sheet or for other corporate purposes. There can be no assurance that such financing will be available on acceptable terms, or at all.

If adequate capital is not available when needed, we may be required to delay, scale back or discontinue research and development programs, reduce commercialization activities, postpone or forgo strategic acquisitions, licensing transactions or other growth opportunities, or otherwise modify our business strategy. In addition, any future equity financing could be dilutive to our stockholders, while debt financing could increase our leverage and impose additional financial and operating restrictions.

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.

We may experience the need to or choose to opportunistically raise additional capital through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or other arrangements. We do not have any committed external source of funds, other than funds already borrowed under our term loan facility of $750 million (the 2026 Term Loan) and an uncommitted additional facility in an aggregate principal amount up to $250 million pursuant to the financing agreement, dated August 2, 2024, as amended on March 18, 2026, that we entered into with Blue Owl Capital Corporation, as administrative agent, and Blue Owl Capital (the Financing Agreement) (see Note 7 – Loan Payable to our consolidated financial statements for more information). The private credit industry and related investments in credit funds have been subject to increased risks, regulatory scrutiny and negative publicity as well as certain high-profile defaults and bankruptcies. Such investments are subject to potential deterioration as adverse changes in macroeconomic conditions and changes in investment strategies may adversely impact the investment. If a significant global market correction or downturn results in a material adverse effect on our lenders or if our lenders are involved in defaults or bankruptcies, it may impair our ability to refinance our 2026 Term Loan or raise additional capital from them, if we found it necessary or desirable to do so. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or products and product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, which could limit our ability to expand our business operations and could harm our overall business prospects.

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

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

We are currently focusing the majority of our resources and efforts on maintaining approval, improving and commercializing BRIUMVI and developing subcutaneous ublituximab and azer-cel for particular indications. Because we have limited resources, we may forgo 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 or target markets for BRIUMVI and our product candidates, we may relinquish valuable rights to our product candidates or programs through collaboration, licensing, or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates or programs. Further, we may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful for which it would have been more advantageous to enter into a partnering arrangement.

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

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

On August 2, 2024, we entered into a term loan facility with Blue Owl Capital Corporation, as administrative agent, HealthCare Royalty and Blue Owl Capital (the Initial Term Loan). In March 2026, we entered into a first amendment to the Financing Agreement to repay in full the Initial Term Loan and enter into the 2026 Term Loan with Blue Owl Capital. The 2026 Term Loan will mature on March 18, 2031 (see Note 7 – Loan Payable to our consolidated financial statements for more information).

All obligations under the Financing Agreement are secured by a lien on substantially all of our assets and the assets of certain of our subsidiaries as guarantors. 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 our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing on acceptable terms;
- requiring the dedication of a substantial portion of our cash flow from operations to service debt, reducing cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business; and
- placing us at a possible competitive disadvantage relative to competitors that are less leveraged or have better access to capital.

To the extent additional debt is added to our current debt levels, the risks described above could increase, including in the ways described below:

- 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 Financing Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the creditors under the Financing Agreement 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 Financing 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, Blue Owl Capital and HealthCare Royalty could accelerate all the amounts due. In the event of an acceleration of amounts due under the Financing 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. Blue Owl Capital Corporation could also exercise its rights as the Administrative Agent to take possession and dispose of the collateral securing the term loan for its benefit, which collateral includes substantially all of our assets and certain of our subsidiaries as guarantors. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

In addition, the Financing Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things (subject to the exceptions provided for in the Financing Agreement):

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

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

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

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Any failure of such depository institution to return any of our deposits upon a liquidation of such institution, or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

Risks Related to Drug Development and Regulatory Approval

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

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

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

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

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

Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that may have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate, through adequate and well-controlled clinical trials, that our product candidate is 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 preclinical 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 or pivotal 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 earlier stages of clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is a 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 assessment of the validity of the study results by applicable regulatory agencies.

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data, such as later 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 top-line, 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 may 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 and progression-free survival, and continuously observed data such as annualized relapse rate have the potential to change with longer follow-up. In addition, as patients continue on therapy, there can be no assurance 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 scope of disclosure we have made or the conclusions we have reached, our ability to obtain approval for, or successfully commercialize, our product or product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

Successful completion of our clinical trials is a prerequisite to submitting a New Drug Application (NDA) or a Biologics License Application (BLA) to the FDA or similar applications for marketing approval to comparable regulatory authorities outside of the U.S. 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 if so, how quickly, we complete clinical trials depends in part upon the rate at which we are able to engage clinical research/trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. We may experience unforeseen events 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 Data Safety Monitoring Boards (DSMBs) or ethics committees (ECs) may not authorize us or our investigators to commence or continue a clinical trial or conduct a clinical trial at a prospective trial site or in a country; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional preclinical 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, DSMBs 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;
- any shifts in the regulatory focus of government agencies;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises, international conflicts in Russia and Ukraine, Iran, the Middle East, and South America, economic instability, or natural disasters;
- regulatory authorities may revise the requirements applicable to our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs, DSMBs or ECs to suspend or terminate the trials, or reports may arise from preclinical 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 clinical hold, 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition to the FDA, the IRB and/or the DSMB for our clinical trials may recommend modification to the study design, refusal for or limitation on additional subjects to participate, or closure of the study entirely based on the IRB's and/or DSMB's interpretation of the benefit-risk of the study. While we develop charters that guide the nature of the IRB and DSMB meetings, their analysis and interpretation of study data occurs independently from us and is wholly within their control. Even if the IRB or DSMB finds no safety concerns and recommends no modifications to the ongoing study, this does not mean the safety profile reported in the study may support a marketing approval or commercial acceptance if marketing approval is granted. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

In addition, changes in regulatory policy could cause us to have to repeat or conduct additional clinical trials or change our clinical development strategy. 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 preclinical or future clinical development programs may harm our business, financial condition and prospects significantly. We may also incur additional costs if enrollment is increased.

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

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

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

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

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

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

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

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

The research, nonclinical and clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, compliant handling, and pharmacovigilance and adverse event reporting of our product or product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities worldwide. In the United States, we are not permitted to market a new 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 regulatory authorities outside of the U.S. 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 regulatory authorities outside of the U.S. exercise extensive control over the pharmaceutical product approval process, including substantial discretion to delay, limit or deny approval of a product candidate for many reasons. During the regulatory review process, the FDA or other regulatory authorities may disagree with or not accept our clinical trial design, may have questions about the potential impact of our study design on conclusions that can be drawn from the data, may interpret results differently than we do, may apply the results of our trials in one disease to the review of a regulatory application for a different disease even if the doses and therapeutic areas are distinct, and may change its view on the criteria that must be met for approval. This could happen even for a protocol used to support a trial that is subject to a Special Protocol Assessment (SPA) agreement with the FDA. There is no guarantee that the FDA will not delay, limit or deny approval of our product candidates in the future.

Furthermore, some of our clinical trials may be conducted as open-label studies, meaning that trial participants, investigators, site staff, some employees of our CROs, and our field-level employees (including 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 at any time prior to making its final decision, even after previous contrary determinations by the FDA. The FDA may also seek the guidance of an outside advisory committee in evaluating (among other things) clinical data and safety and effectiveness considerations prior to making its final decision. These issues could cause a delay in the FDA's review, lead the FDA to deny approval, or lead us to withdraw a regulatory application.

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

- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities outside of the U.S. that a product candidate is tolerable and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care or the patient population, is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable regulatory authorities outside of the U.S. for approval;
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- We may submit additional information to the FDA which the FDA determines constitutes a major amendment to the application and thereby extends the goal date for determination of approvability of the application;

- the FDA or comparable regulatory authorities outside of the U.S. 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 regulatory authorities outside of the U.S. may identify issues related to the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for commercial supplies; during the course of review, the FDA or regulatory authorities outside of the U.S. may raise issues and request or require additional preclinical, clinical, chemistry, manufacturing, and control, 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 Prescription Drug User Fee Act (PDUFA) goal date or at all to satisfy the FDA or regulatory authorities outside of the U.S.;
- the approval processes of the FDA or comparable regulatory authorities outside of the U.S. may significantly change in a manner rendering our clinical data insufficient for approval; or
- interruptions or delays in the operations of the FDA and regulatory authorities outside of the U.S. as a result of global health crises, inadequate government funding, political conditions or economic crises, international conflict, or natural disasters may negatively impact review, inspection, and approval timelines.

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

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

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

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

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

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes FDA or other comparable regulatory authorities 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 may evaluate and pursue orphan drug designation for indications that could be eligible, we may never receive such designation. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations or obtain orphan drug exclusivity. In addition, the U.S. Orphan Drug Act may be subject to amendments that could reduce the period of marketing exclusivity or change the qualifications for orphan drug designation, which could adversely impact our products or product candidates that have or may be eligible for orphan drug designation.

We are conducting clinical trials and anticipate conducting additional clinical trials for our product and product candidates at sites outside the United States, and trials conducted in such locations or clinical trial activities in such locations may be impacted by political conditions, including international conflict.

Many of our clinical trials utilize international clinical research sites. We work with what we believe are reputable CROs and clinical research sites in conducting our studies internationally. Nevertheless, there can be heightened challenges to monitoring and oversight of global clinical trials and sponsors are subject to the risk that fraud, misconduct, incompetence, unexpected patient variability and other issues affecting the reliability, quality, and outcome of studies. Such challenges, if they were to occur, could negatively impact trial results, and depending on the circumstances and scope of concerns could potentially even prevent a trial from being useful or acceptable for regulatory approval. If such events were to occur with respect to any of our trials (and in particular with respect to registration-directed studies), they would have a substantial negative impact on our business.

In addition, our clinical studies with sites outside the United States may be adversely impacted by international conflict, including in Russia and Ukraine, in Iran and the Middle East, and in South America. The conflict in Russia and Ukraine and its impact on neighboring countries may adversely affect clinical trial sites for our programs. While no clinical trials are currently enrolling patients in Russia, we do have actively enrolling clinical trials in Ukraine, and there are a number of trial subjects in long-term treatment and follow-up in both countries. The political and physical conditions in Russia and Ukraine have disrupted our ability to supply investigational drug product to impacted sites; impacted patients' ability to partake in our clinical trials and our ability to gather data on those patients, including long-term follow-up data; impacted our ability to audit clinical trial sites in these territories, and resulted in suspension of clinical trial activities at impacted sites. Furthermore, the United States and other countries have imposed sanctions against Russia and other restrictions from doing business with certain Russian companies and financial institutions. Our ability to conduct clinical trials in Russia, Ukraine and elsewhere in the region may also become restricted under applicable sanctions laws. Geopolitical conflicts and related government responses have resulted in global economic instability, which could affect our supply chain and commercialization efforts. While we currently do not believe such conflicts will have a material impact on product development or our overall business, given the evolving situation and the related geopolitical and economic uncertainties, the full impact of the conflict remains uncertain.

The FDA and other comparable regulatory authorities outside of the U.S. may not accept data from trials conducted in locations outside of their respective jurisdictions.

We have been conducting, and may continue to conduct, clinical trials globally. The acceptance of study data by the FDA or other comparable regulatory authorities outside of the U.S. from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions, which may include conditions related to the applicability and verifiability of the data and cooperation with foreign regulatory agencies. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any U.S. or regulatory authority outside of the U.S. would accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable regulatory authority outside of the U.S. does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

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

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

We currently do not have any manufacturing capabilities of our own and we rely on third-party contract manufacturers for the clinical and commercial supply of our products. We have established a contract manufacturing relationship with Samsung Biologics for our primary clinical and commercial supply of BRIUMVI, and a secondary contract manufacturing relationship with FUJIFILM Diosynth Biotechnologies. As with any supply program, obtaining materials of sufficient quality and quantity to meet the requirements of the market demand for BRIUMVI and our development programs cannot be guaranteed and we cannot ensure that we will be successful in these endeavors.

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

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

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

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

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

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

We may be unable to successfully develop, obtain regulatory approval for, or commercialize a subcutaneous formulation of our approved intravenous product, which could limit our ability to expand our market opportunity and patient reach.

We are conducting a Phase 3 trial evaluating subcutaneous ublituximab, which is approved in its intravenous (IV) form for the treatment of RMS. While IV BRIUMVI has demonstrated clinical benefit and gained commercial traction, development and commercialization of a subcutaneous version of ublituximab presents unique scientific, formulation, clinical, pharmacologic, manufacturing, regulatory, and operational challenges.

In order to rely on the benefit and risk profile established for IV BRIUMVI in previously conducted pivotal clinical trials, the subcutaneous form of ublituximab requires optimization of pharmacokinetics to attain equivalent exposure to ensure that efficacy and safety are maintained at levels comparable to the approved IV formulation. Pharmacokinetic (PK) and pharmacodynamic (PD) effects may be reduced or altered when administered subcutaneous, which could create significant challenges in the development of a subcutaneous formulation of ublituximab. There is also a risk that systemic exposure, tissue distribution or tissue reactions differ in ways that lead to unforeseen efficacy issues, such as reduced clinical benefit or safety or tolerability issues, including injection site reactions or immunogenicity. These issues may not be apparent in early cuts of clinical data and have the potential to become present or increase with longer-term follow-up. Clinical development of a new formulation often takes place alongside process and formulation development, such that the form of the product evaluated in early-stage testing may not be the final form of the product evaluated in late-stage testing or intended to be commercialized, as is the case for subcutaneous ublituximab development. Furthermore, while early phase clinical trials can provide a general understanding of the bioavailability and tolerability of a subcutaneous product, they are limited in patient number and duration of follow-up, with the pivotal regimen determined through PK/PD modeling and projections. Such differences in safety, efficacy or PK/PD may not be observed until later stage clinical studies with the final formulation of subcutaneous ublituximab.

Furthermore, the development of a subcutaneous formulation, including subcutaneous ublituximab, typically requires additional clinical studies, including bridging studies and the use of delivery devices (e.g., auto-injectors or prefilled syringes), which may introduce new technical, supply chain, or regulatory challenges. Developing drug-device combinations is complex and there can be no guarantee that the clinical properties of ublituximab will not be altered when administered via an auto-injector device. Regulatory agencies may not consider bioequivalence sufficient for approval or may require additional data to demonstrate comparable effectiveness or safety, especially if the subcutaneous formulations have analytical differences. While the primary outcome of the pivotal clinical trial is to establish non-inferior exposure, differences in other clinical properties including but not limited to PD effect, safety, tolerability, and immunogenicity may occur. In such cases, while the primary outcome of the clinical study may be met, regulatory agencies may still consider such a product not pharmaceutically equivalent.

Subcutaneous formulation may involve higher concentration of the existing IV product, as in the case of subcutaneous ublituximab, which presents technical and analytical challenges. Concentrated products will have increased viscosity, which will result in decreased yield in the manufacturing process and may increase the cost of goods compared to that of IV BRIUMVI. The high concentration formulations currently under evaluation may not prove to be as stable as the IV BRIUMVI product. If the subcutaneous formulation is determined to have a shorter shelf life, we may require more inventory or reassess the commercial feasibility for distribution. If a shorter shelf life is determined, we may require more inventory or may determine that current products are not commercially feasible for distribution. Additionally, new supply chains have been and will continue to need to be developed, which adds complexity and magnifies the concerns around reliance on third parties, including establishing new vendors, their timeliness and quality of performance and potential for future supply constraints, and other limitations. Furthermore, the altered physical properties of the subcutaneous material have resulted in certain analytical differences from IV BRIUMVI that may require the development of new analytical methods for product characterization and release, if the current analytical methods used for IV BRIUMVI prove to be inadequate to characterize subcutaneous ublituximab. Analytical method development is a complex task that has both technical and regulatory implications, and there can be no assurances given that such development will be successful or be completed in a timely manner.

Even if approved, we cannot guarantee that the subcutaneous formulation of ublituximab will be successfully commercialized or achieve the same level of adoption as the IV formulation. Development, approval, and commercialization of the subcutaneous formulation of ublituximab will take considerable time and will be subject to completion with existing therapies and new therapies that may become available in the future. Failure to develop or obtain regulatory approval for a subcutaneous formulation, or to successfully commercialize it if approved, could materially limit our growth in markets that favor self-administration and reduce our competitive positioning relative to other self-administered therapies.

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, 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 to and affordability of prescription drugs. The Affordable Care Act (ACA) made significant changes to the U.S. healthcare system, which included expanding healthcare coverage through Medicaid and implementation of the individual health insurance mandate; changing coverage and reimbursement of drug products under Medicare, Medicaid and 340B government programs; imposing an annual fee on manufacturers of branded drugs; and expanding government enforcement authority. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. The One Big Beautiful Bill Act (OBBBA) has enacted, among others, changes to eligibility requirements for premium tax credits, which is expected to result in less coverage in the ACA's health insurance marketplace (Marketplace) over the next few years. The ACA premium tax credits expired at the end of 2025, which resulted in an additional loss of coverage for an estimated 24 million people that were previously enrolled in insurance plans obtained through the Marketplace. In addition, the OBBBA has made other changes to the enrollment and eligibility requirements for Medicaid, which is expected to result in the loss of coverage for certain individuals currently enrolled in Medicaid programs. Further, the Centers for Medicare & Medicaid Services (CMS) has proposed two mandatory payment model pilots, the Guarding U.S. Medicare Against Rising Drug Costs Model, focused on Part D drugs, and Global Benchmark for Efficient Drug Pricing, focused on Part B drugs, which will require pharmaceutical companies to pay additional rebates on certain medicines, including central nervous system agents for the treatment of multiple sclerosis, whose U.S. net-of-discount prices exceed those in certain other countries.

We are uncertain of the impact or outcome of potential executive orders, rescission of rules and policy statements, or new legislation to be enacted, especially with regards to the healthcare regulatory and policy landscape, or the impact they may have on our business. In addition, 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 could have an adverse impact on our anticipated product revenues. There have been several U.S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs and reform government health care program reimbursement methodologies for prescription drugs. In September 2024, CMS issued a final rule titled "Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program" which may impact our reimbursement and rebate strategy. The ACA expanded the 340B drug discount program to additional facilities for outpatient drugs. These facilities may purchase drugs at the discounted price provided to Medicaid and dispense drugs to people with commercial insurance coverage. This program has greatly expanded over time with qualifying facilities establishing relationships with contract pharmacies, which has continued to exert downward pressure on price and profitability of outpatient medicines. Any changes to Medicaid required rebates could also affect our 340B pricing. Other aspects of the 340B program are subject to ongoing litigation, the resolution of which could impact the scope of the 340B program.

Moreover, the Inflation Reduction Act (IRA) included, among other provisions, several measures intended to lower the cost of prescription drugs and related healthcare reforms. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and replaces the Part D coverage gap discount program with a new discounting program. If any of our approved products are subject to price negotiations, it could, among other things, lead to lower revenues prior to the expiry of intellectual property protections. The Medicare drug price negotiation program is currently subject to legal challenges and therefore, its outcome remains uncertain.

Further, executive orders were signed to implement MFN drug pricing policies designed to align certain prescription drug prices in the U.S. to lower prices available in other countries. If such MFN policies are implemented, changes to drug pricing are expected to affect the profitability of pharmaceutical and biotech companies in the U.S. as well as in other countries, as a price referencing policy to the U.S. market could make it commercially unviable to commercialize a drug product in a price constrained market. The details of the proposed policies are unclear and the final terms and impact remain uncertain, and may pose long-term risks to our business and our future commercialization plans of our products and product candidates. In addition, the Fair Prescription Drug Prices for Americans Act was re-introduced in May 2025 and proposes to cap the retail list price of prescription drugs and biological products in the United States at the average retail list price for such product among certain countries. Although it is uncertain if these pricing proposals will take effect, reducing drug prices remains a bipartisan effort and, if made effective, could significantly impact coverage, pricing, and reimbursement for any approved product. These and other similar developments could significantly limit the degree of market acceptance of our products or any of our product candidates that receive marketing authorization. We expect that healthcare reform measures that may be adopted in the future may result in increased financial liability for manufacturers 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, the FDA's Biosimilar Action Plan and current Biosimilar User Fee Amendments provide a detailed account of the agency's strategic priorities to improve the efficiency of the biosimilar and interchangeable product development and approval process and support robust competition. In the event there is a modification to the biologic exclusivity period, other applicable regulatory exclusivity periods or other steps taken to facilitate biosimilar approvals, we could experience competition to any products for which we receive FDA approval at an earlier time than currently anticipated.

Individual states are experiencing significant economic pressure within their respective Medicaid programs and responding to public concern over the cost of healthcare. Several states 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 Prescription Drug Affordability Boards, some with the ability to impose price controls on state drug purchases, 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 net pricing.

There is also a great degree of uncertainty regarding how U.S. Supreme Court decisions, including Loper Bright Enterprises v. Raimondo and Corner Post, Inc. v. Board of Governors of the Federal Reserve System, will impact FDA's enforcement and decision-making authority of regulatory agencies, including those of the FDA. Loper Bright explicitly overturned Chevron deference, which previously gave judicial deference to administrative action by agencies in the executive branch. Further, the Supreme Court's decision in Corner Post may result in challenges to FDA decisions by new litigants long into the future, resulting in greater uncertainty about our continued operations. In February 2025, an executive order was signed asserting greater authority over all federal agencies, including those established by Congress as independent from direct presidential control. The executive order may lead to continued delays, if not cancellations, of pending and proposed regulations at federal agencies and introduces uncertainty as it subjects all significant regulatory actions by the agencies to the President's supervision and control. We cannot predict the impact that such executive order, any future executive orders or legislation implementing executive orders may have on our business or our results of operations. Furthermore, legislative and regulatory proposals have been made to expand post-approval requirements, make changes to the Orphan Drug Act and related guidance, reform the 340B Drug Pricing Program, and restrict sales and promotional activities for drugs, which have presented both opportunities and challenges for drug manufacturers participating in the program.

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. The FDA has made significant policy changes affecting research, testing, regulatory approval or clearance, manufacturing and marketing of FDA-regulated products. The FDA has also adopted certain programs, including the PreCheck Program and Commissioner's National Priority Review Voucher Program, designed to increase domestic production of FDA-regulated products, and increased enforcement activities by issuing larger numbers of warning letters to pharmaceutical companies related to violation of regulatory standards governing direct-to-consumer advertising. 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. Changes to healthcare regulation and policies, agency priorities, enforcement initiatives and focus, and coverage and reimbursement for healthcare products and services may be sudden and unexpected, and we may experience increased costs to monitor for such changes and respond to any new requirements affecting our business and operations.

In many international markets, including the EU, the government regulates prescription drug prices, patient access, and/or reimbursement levels to control the biopharmaceutical budget of their government-sponsored healthcare system. The EU 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 healthcare expenditures. These measures vary by country and may include, among other things, non-coverage decisions, patient access restrictions, international price referencing, mandatory discounts or rebates, and cross-border sales of prescription drugs. These measures may adversely affect our ability to generate revenues or commercialize our product or product candidates in certain international markets.

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

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

Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, which affects average review times at the FDA. Significant workforce reductions and reorganizations at several U.S. health agencies, including the FDA, the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention and the National Institutes of Health, have impacted, and may continue to impact, the FDA's ability to review and approve new medicines and conduct necessary inspections.

In addition, government funding of the FDA, SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable, and spending allocation priorities may undergo significant changes through congressional budgeting and appropriations processes. Disruptions at the FDA and other agencies may also extend the time necessary for new drugs to be reviewed and/or approved, including delays in PDUFA reviews and related activities, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough employees, experience substantial funding cuts and pause or delay critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to review and process our regulatory submissions in a timely matter, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. This law applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business;
- 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. For example, life sciences companies have faced enforcement actions under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product, among other activities. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute or the Federal Food, Drug, and Cosmetic Act (FDCA) constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, has fraud provisions that impose criminal and civil liability for knowingly and willingly executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, 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. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs, or integrity oversight and reporting obligations to resolve allegations of non-compliance;

- the Physician Payments Sunshine Act under section 6002 of the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to monitor and report certain information related to payments and other transfers of value to and the ownership and investment interests of physicians and certain other healthcare providers as well as teaching hospitals to the federal government for redisclosure to the public. CMS has the potential to impose penalties for violations of the Physician Payments Sunshine Act, depending on the circumstances, and reported payments also have the potential to draw scrutiny to our relationships with health care practitioners and academic medical institutions, which may have implications under the Anti-Kickback Statute and other healthcare laws;
- HIPAA, as amended by HITECH and other amendments, 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. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
- the FDCA and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the Drug Supply Chain Security Act, 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 that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; marketing restrictions and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

As we continue commercialization of BRIUMVI, we are taking steps to provide patient support services to help patients access the product. Our patient support programs are administered in conjunction with a patient support program vendor and other third parties. There has been heightened scrutiny by government enforcement agencies, including, by the HHS Office of Inspector General and the U.S. Department of Justice in drug manufacturers' product and patient assistance programs and the operation of such programs, including reimbursement support services, and investigations into these programs have resulted in significant civil and criminal settlements. 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.

We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and agents may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA or foreign regulatory authority requirements, including those laws that require the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our 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 be in compliance with such laws or regulations.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Advisory Opinions, and Special Fraud Alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal Anti-Kickback Statute are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations. Any action against us for violation of these laws, 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.

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

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

Within the United States, HIPAA, as amended by HITECH, establishes a federal "floor" with respect to privacy, security, and breach notification requirements as it pertains to protected health information subject to HIPAA and does not supersede any state laws insofar as they are broader or more stringent than HIPAA. There are numerous other laws, regulations and legislative and regulatory initiatives at the federal and state levels addressing privacy and security of personal data. Depending on the data we receive, we may be subject to federal and state privacy-related laws that may be more restrictive or contain different requirements than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties and requirements related to such data. HIPAA affects the ability of healthcare providers and other entities with which we may interact, including clinical trial sites, to disclose patient health information to us. Under Section 5(a) of the Federal Trade Commission Act (FTCA), the Federal Trade Commission (FTC) expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC has asserted authority and issued enforcement actions in response to actual or perceived unfair or deceptive practices by a company in the handling of consumer information. Medical data, and health information more generally, is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act, as amended (CCPA) imposes data privacy obligations for covered companies and provides privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California privacy protection agency is authorized to issue substantive regulations that could result in increased privacy and information security enforcement. Data privacy and cybersecurity are also areas of increasing state legislative focus. Among other things, new state-specific laws create additional data privacy obligations for covered companies and provide new privacy rights to state residents, including the right to opt out of certain disclosures of their information. Draft regulations implementing certain of the state statutes have been published, but many questions remain as to how all of the new statutes will be interpreted. These laws are rapidly changing, and tracking, analyzing and complying with such laws require significant time and expenses and can materially impact our business. We cannot predict where new legislation might arise, the scope of such legislation, or the potential impact on our business and operations. New federal and state laws and regulations that may be enacted in the future may require us to modify our data processing practices and policies, incur substantial compliance-related costs and expenses, and otherwise suffer adverse impacts on our business.

Numerous other jurisdictions regulate the privacy and security of personal data, such as the General Data Protection Regulation and the United Kingdom equivalent thereof (collectively, GDPR). The GDPR increases obligations with respect to clinical trials conducted in the European Economic Area (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 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 we experience a reportable cybersecurity incident or data breach that is subject to any data privacy and security laws or if our operations are found to otherwise 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, litigation and the curtailment or restructuring of our operations, which could adversely affect our ability to operate our business, our reputation and our financial results. In the U.S., most state data breach notification laws consider violations to be unfair or deceptive trade practices and give the relevant state attorneys general (AGs) the authority to levy fines or bring enforcement actions. Such AG investigations—which are often time consuming, expensive, and burdensome—may lead to a resolution agreement, whereby certain obligations are performed, and reports are made to the AG for a period of time, and/or civil penalties. Class action lawsuits against companies which experience a data breach involving personal information are also common. Additionally, the SEC and many jurisdictions have enacted or may enact laws and regulations requiring companies to disclose or otherwise provide notifications regarding data security breaches. 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 or perceived 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.

We, directly or through our third-party service providers, may adopt, use or incorporate artificial intelligence (AI) technology and capabilities into the information technology systems or software that we use in our business and operations. Defects in such AI technology or related security breaches, loss of data and other disruptions as well as changes in implementation standards and enforcement practices under a rapidly evolving regulatory framework for AI technology may adversely affect our business and operations and potentially expose us to increasing liability.

We, directly or through our third-party service providers, may adopt, use or incorporate AI technology and capabilities into information technology systems, software or other tools to help us operate our business more efficiently than existing industry tools. Use of AI technology may introduce operational, cybersecurity, privacy, intellectual property, data-integrity, bias and quality-control risks, including risks arising from inaccurate outputs, inappropriate reliance on AI-generated content, unauthorized use or disclosure of confidential or personal information, and failures by vendors to develop, deploy or monitor AI tools in accordance with applicable requirements. The regulatory framework for AI technologies is rapidly evolving as many federal, state and foreign government bodies and agencies have introduced, enacted or are considering additional laws, regulations, executive orders, guidance and other enforcement initiatives that may affect the development, procurement, deployment and use of AI technology. In addition, existing laws and regulations may be interpreted in ways that would affect the use of AI in our business.

In the EU, the Artificial Intelligence Act (EU AI Act) establishes a comprehensive, risk-based governance framework for AI in the EU market. The EU AI Act and developing interpretation and application of the GDPR in respect of automated decision making, together with developing guidance and/or decisions concerning the impact of AI technology on data privacy may affect our use of AI technologies. Further, interpretation and implementation of intellectual property protection in the field of AI are rapidly evolving and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI and relevant system inputs and outputs. If we fail to obtain protection for intellectual property rights for any of our intellectual property that may incorporate or be developed using AI technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products that could adversely affect our business, reputation and financial condition. Further, other parties may have, or in the future may obtain, patents or other proprietary rights that would prevent, limit or interfere with our ability to use any AI technologies that we may develop or use in our business.

The evolving regulatory framework for AI technologies and related implementation standards and enforcement practices remain uncertain, and we cannot yet determine the impact that current or future laws, regulations, standards, agency guidance, enforcement priorities or market perception of such requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. We may need to expend resources to adjust our systems in certain jurisdictions if the laws, regulations, decisions or guidance are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, decisions and/or guidance interpreting existing laws could be significant and would increase our operating expenses. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

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 regulatory authorities outside of the U.S. and other government agencies, we are exposed to liability risks under the Foreign Corrupt Practices Act (FCPA) or similar anti-bribery laws. We may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U.S. and the EU, including applicable export control regulations (focusing on national security-related technologies, including biotechnology), economic sanctions on countries and persons, customs requirements, and currency exchange regulations, which we collectively refer to as Trade Control Laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, similar anti-bribery laws, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC may also suspend or bar issuers from trading securities on U.S. exchanges, including the Nasdaq Stock Market, for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by the U.S. or other authorities, could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Any product for which we obtain marketing approval, including BRIUMVI, could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our 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 outside of the U.S. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding promotional interactions with healthcare professionals.

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

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

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

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

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

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

Our research and development activities could be affected or delayed as a result of shortages in animal availability or possible restrictions on animal testing. Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

Certain laws and regulations may require us to test our product candidates on animals before initiating clinical trials involving humans. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfill regulatory requirements may materially adversely affect our ability to advance our preclinical and clinical programs and successfully develop our product candidates, which result in significant harm to our business.

Additionally, animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed or become more expensive. The Animal Welfare Act (AWA), is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines, penalties and adverse publicity, and our operations could be adversely affected.

Risks Related to Our Dependence on Third Parties

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

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

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

Whether conducted through a CRO or through our internal staff, we are solely responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or other enforcement actions that may include civil penalties or criminal prosecution. We and our CROs are required to comply with regulations, including GCP guidelines for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable regulatory authorities outside of the U.S. 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 regulatory authorities outside of the U.S. 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 Contract Manufacturing Organizations (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 within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In July 2023, we entered into a Commercialization Agreement (the Commercialization Agreement) with Neuraxpharm, pursuant to which Neuraxpharm has the right to commercialize BRIUMVI in certain markets outside of the U.S. In February 2024, BRIUMVI was first made available in the European market by Neuraxpharm in Germany and is now commercially available in several other countries in the EU, outside the EU and in the United Kingdom. In addition to the Commercialization Agreement, we may enter into collaboration arrangements with other collaboration and commercialization partners.

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

- decisions by our collaboration and commercialization partners to terminate their collaboration or commercialization agreements with us for reasons specified in the collaboration or commercialization agreements, including our breach;

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

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

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

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

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund related expenses. Therefore, 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 proposed collaborator's resources and expertise, the terms and conditions of the proposed collaboration with a third party, 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 comparable regulatory authority outside of the U.S., 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 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 favorable terms to us, 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 favorable 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 we may ultimately not be able to generate revenue from their sales.

Risks Related 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. At the same time, if the scope of our patent protection is too broad, our competitors may challenge the validity and enforceability of our patents.

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

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

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

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

These risks and uncertainties include the following:

- the patent applications that we or our licensors file may not issue as patent;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the United States converted from a first-to-invent to a first-to-file system. If we do not win the filing race, we will not be entitled to inventive priority;

- our competitors, many of whom have substantially greater resources than we do, and many of whom have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to file new patent applications covering our products, or make, use, and/or sell our products either in the United States or in international markets;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns, which could limit our ability to fully monetize our intellectual property rights; and
- countries other than the United States may have less restrictive patent laws than those of the United States, allowing foreign competitors to exploit such less restrictive patent laws to make, use, and/or sell competing products in their respective jurisdictions.

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

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

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

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

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

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

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

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections may 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 methods in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

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

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

Depending on the timing, duration, and specifics of any FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act permits 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 fourteen years from the date of product approval by the FDA, and only one patent covering the approved product may be extended.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ability to utilize our net operating loss (NOL) 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. Although we have recently completed a 382 study, we may have experienced additional ownership changes after the completion of this study, 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 a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset our taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. Accordingly, even if we attain profitability, we may be unable to use a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

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

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

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

Our internal information technology systems, or those of our third-party CROs, CMOs, or other contractors, vendors, or consultants, are vulnerable to failures or 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, vendors, and consultants are vulnerable to damage from viruses, unauthorized access, security breach or incidents, natural disasters, terrorism, war and telecommunication and electrical failures. Security breaches include, but are not limited to, deployment of harmful malware, ransomware, denial-of-service attacks, vendor breaches, supply chain attacks, data breaches by employees, insiders or others with authorized access, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our and our third-party service providers' systems and the information stored on such systems. Security breaches can also include phishing attempts or e-mail fraud to cause unauthorized payments or information to be transmitted to an unintended recipient, or to permit unauthorized access to systems. Although we have experienced security events in the past, the impact on our operations and financial condition has not been material. High-profile security breaches at other companies and in government agencies have increased in frequency and scope, and we expect such cybersecurity threats to continue and become more sophisticated. Threat actors, including nation state attackers, could also use AI for malicious purposes, increasing the frequency and complexity of their attacks. A significant security breach or incident could cause our systems to fail, compromise the information stored on such systems, or cause significant business interruptions, which could result in a material disruption of our operations, financial loss, or reputational harm. For example, the unauthorized access to, disclosure of, or loss of clinical trial data for our drug candidates could result in delays in our regulatory approval efforts, violate healthcare privacy laws and regulations, result in legal claims or proceedings, and significantly increase the cost of remediation. We have invested in protections and monitoring practices of our data and information technology systems to reduce these risks and expect to continue to 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 and changes in government regulations could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Key national economies, including the United States, have been affected from time to time by economic downturns or recessions, supply chain constraints, high inflation, restricted credit, poor liquidity, reduced corporate profitability, debt, equity and foreign exchange market volatility, bankruptcies, high interest rates, high unemployment rates and overall uncertainty with respect to the economy. In particular, fluctuating and/or high interest rates in the United States to respond to inflationary pressures and market volatility may result in a general economic downturn or recession, which could reduce our ability to raise additional capital when needed on acceptable terms, if at all, and negatively impact our results of operations and financial condition.

Likewise, the capital and credit markets may be adversely affected by geopolitical conflicts and global sanctions imposed in response thereto. Other international events such as trade disputes, increased tariffs and countermeasures by affected countries, leadership changes and political and military conflicts could also adversely affect global financial activity and markets and could negatively affect the U.S. economy. The U.S. has imposed increased tariffs on certain countries, focusing on those with which it has the largest trade deficits. Other countries have responded, and may continue to respond, by announcing retaliatory tariffs on U.S. imports. In addition, the U.S. Department of Commerce initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (Section 232). Following the Section 232 investigations and other policy changes related to MFN drug pricing, in April 2026, an executive order was issued, followed by additional guidance and clarification from the U.S. Department of Commerce in September 2026, seeking to impose up to a 100% tariff on imported patented pharmaceuticals, subject to certain exceptions for certain products and for companies that have an agreement regarding MFN drug pricing or onshore manufacturing. For example, effective September 29, 2026, certain of our commercial drug substances and drug products imported into the United States from our CMOs became subject to a 15% tariff. The terms and effects of such tariffs, if and as they are implemented, and other policy changes are uncertain and could have adverse implications on drug pricing, drug production levels and patient access, and may result in supply chain or other operational disruptions. Further, if we are required to change our current manufacturing partners or suppliers now or in the future in order to avoid such tariffs, the terms of new agreements that we may enter into may not be favorable to us and related operational disruptions may heighten manufacturing and compliance risks and derail commercialization plans. The tariffs have disrupted, and may continue to disrupt, the global markets and escalate tensions between the U.S. and other countries. The extent of the impact of geopolitical conflicts, sanctions and increased tariffs on our business specifically, or on the U.S. market and global economy generally, are uncertain and unpredictable, and could adversely affect our business, financial condition and results of operations as well as impact our ability to raise capital.

The United States may also enact other regulations or policies that affect trade or otherwise impact the pharmaceutical industry by restricting U.S. pharmaceutical companies from contracting with certain countries for the development, research or manufacturing of pharmaceutical products. In December 2025, the BIOSECURE Act was signed into law as part of the Fiscal Year 2026 National Defense Authorization Act, which restricts U.S. government agencies from purchasing or obtaining certain biotechnology equipment or services from “biotechnology companies of concern” (BCC); entering, extending or renewing a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or granting government funds or loans for such biotechnology equipment or services provided by a BCC. While we do not currently anticipate any material impact from the BIOSECURE Act, it may have significant implications for U.S. companies with government contracts that obtain biotechnology equipment or services from a BCC, including contracts with the Department of Veterans Affairs, and any related impact on reimbursement under Medicaid and Medicare Part B.

Additionally, the Federal Reserve Board (FRB) and other major central banks have been consistently removing or reducing monetary accommodation, increasing the risk of recession and also potentially negatively impacting asset values and credit spreads that were boosted by extraordinary monetary stimulus. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our marketed product and services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions, could adversely impact our business.

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

We are exposed to the risk that our employees, principal investigators, CROs, CMOs, and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

Our officers, directors, employees and consultants and certain other persons are also subject to insider trading rules prohibiting the use of material nonpublic information to purchase, sell or otherwise trade in our securities or those of other companies. In August 2026, the SEC and the FDA announced a memorandum of understanding to establish a formal framework for interagency information sharing, coordination and protocols for exchange of nonpublic information regarding FDA-regulated products and activities, including results of clinical trial results, status of FDA review, product approvals, facility inspection observations, and other matters within the FDA's regulatory authority. Such developments may increase the risk that our directors, officers, employees, principal investigators, CROs, CMOs, consultants, or other insiders with access to material nonpublic information related to FDA regulatory matters could become the subject of SEC enforcement actions for insider trading or related violations. Although such persons are required to comply with our Insider Trading Policy, there can be no assurance that these measures will be effective in preventing or detecting all instances of insider trading, misuse of material nonpublic information, or other misconduct.

In addition, 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. For example, we have made a significant investment in direct-to-consumer (DTC) advertising for BRIUMVI, a highly regulated form of marketing subject to significant scrutiny from FDA and other regulatory bodies. Television advertising in particular has undergone increased scrutiny, and we, along with all sponsors of marketed drugs, have received notification from the FDA mandating compliance with applicable regulations. To date, while we believe that all of our marketing efforts, including our direct-to-consumer advertising, comply with FDA regulations, regulators may adopt a more conservative viewpoint on advertising or future regulations may be adopted which restrict or prohibit our ability to directly advertise to consumers.

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. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The OBBBA reinstates the option to deduct domestic research and development expenditures in the year incurred, commencing with tax years beginning after December 31, 2024. Foreign research and development expenditures remain subject to the 15-year capitalization and amortization requirement. The OBBBA also includes other significant provisions, including tax cut extensions and modifications to the international tax framework. While we continue to evaluate the impact of these legislative changes as additional guidance becomes available, uncertainty remains regarding the timing and interpretation by tax authorities in affected jurisdictions. 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.

Any changes in regulations or policies related to taxation and importation, including as a result of increased tariffs, could adversely impact the global economy and our operating results. To the extent that future U.S. tax policy changes have a negative impact on us, including as a result of related uncertainty, these changes could adversely impact our business, results of operations and financial position.

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 our stock at a profit.

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

- reception and success of BRIUMVI in the U.S. market;
- reception and success of BRIUMVI in any jurisdiction outside of the U.S. in which it is currently approved, or in any other jurisdiction in which it might be approved or launched;
- publicity regarding actual or potential clinical results relating to our product or products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by us or our competitors;
- any delay in our regulatory review for products and product candidates we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, a change to the projected approval date, scheduling of an advisory committee meeting or issuance of a "refusal to file" letter;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- announcements of technological innovations by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments in the United States and foreign countries;
- litigation or arbitration;
- economic, political and market conditions or other crises and other external factors such as the disruptions in the global economy caused by global health crises and geopolitical conflicts in Russia and Ukraine, Iran and the Middle East, and South America;
- 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;
- our repurchase of shares of our common stock pursuant to our share repurchase program;
- sales of our common stock by us; and
- the occurrences of any of the other risks described in this Quarterly Report on Form 10-Q.

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

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

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

Our reputation and the reputation of our brands, including the perception held by our customers, end-users, business partners, investors, other key stakeholders and the communities in which we do business are influenced by various factors. The impact of environmental, social and governance (ESG) regulations and policies may change customer preferences, demands and requirements, and if we are not able to meet changing expectations, our ability to compete may be adversely affected and our reputation or the reputation of our brands may suffer. Such damage to our reputation and the reputation of our brands may negatively impact our business, financial condition and results of operations. In addition, negative or inaccurate postings or comments on social media or networking websites about us or our brands, including as a result of collaborations with third parties, could generate adverse publicity that could damage our reputation or the reputation of our brands or harm our relationships with customers, end-users, business partners, investors, or other key stakeholders. If we are unable to effectively manage real or perceived issues, including concerns about product quality, safety, corporate social responsibility or other ESG matters, sentiments toward us or our products could be negatively impacted, and our financial results could suffer.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, supply chain, results of operations, financial condition and growth prospects.

We believe that natural events beyond our control or climate change related regulations or market measures to address climate change have the potential to negatively affect our business, results of operations, financial condition and growth prospects. Since we currently rely on single contract manufacturers to produce our commercial products, extreme weather and sea level rise pose physical risks to the facilities of our manufacturing partners. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and operational disruptions caused by such natural disasters and extreme weather events. Loss of access to the facilities of our manufacturing partners may result in increased costs, delays in the development of our products or interruption of our business operations. Any disaster recovery and business continuity plans that our or our third-party manufacturers have in place may prove inadequate in the event of a serious natural disaster or similar event. We may incur substantial expenses as a result of the limited nature of these disaster recovery and business continuity plans, which could have a material adverse effect on our business.

In addition, the long-term effects of climate changes on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify the existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, we cannot assure you that such insurance coverage will be sufficient to satisfy any damages and losses we or any of our third-party vendors may directly or indirectly incur. Further, new legal or regulatory requirements to address climate change may adversely affect our supply chain, increase operating costs, including costs of electricity and energy, as well as compliance and monitoring costs and reporting obligations.

Our ability to pay dividends, if any, is limited, and our stockholders may not receive any return on investment unless they sell their common stock.

We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. However, any future determination relating to the use of our future earnings, including the declaration, amount and payment of any future dividends on shares of our common stock, if any, will be made at the discretion of the Board of Directors and will depend on a number of factors, including capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that the Board of Directors may deem relevant. In addition, under the Financing 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, our stockholders may not receive any return on investment unless they sell their common stock.

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

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

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

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

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

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal control over financial reporting. These efforts to comply with Section 404 will require the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that material weaknesses will not be identified when we test the effectiveness of our control systems. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. If we are unable to further implement and maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses, negatively affect investor confidence in our financial statements and adversely impact our stock price. In addition, any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods.

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. Pharmaceutical companies in particular 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 any suits in which we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle any 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.

We cannot guarantee that our stock repurchase program will be further consummated or will enhance stockholder value. Our share repurchase program could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock.

In September 2025, we announced that we completed our previously authorized $100 million share repurchase program and our Board of Directors authorized a new share repurchase program of up to an additional $100 million of our outstanding shares of common stock. In March 2026, the Company's Board of Directors authorized an increase to its share repurchase program from $100 million to $300 million. We intend to repurchase shares of our common stock from time to time, as authorized by our Board of Directors, through open market purchases, in privately negotiated transactions or by other means, including through the use of trading plans intended to qualify under Rule 10b5-1 under the Exchange Act, in accordance with applicable securities laws and other restrictions. The timing and the amount of stock repurchases in the share repurchase program will be determined by our management, based on its evaluation of factors including business and market conditions, corporate and regulatory requirements, and other considerations. The share repurchase program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any amount of our common stock. For more information about our share repurchase activities for the year ended December 31, 2025 and the three and nine months ended September 30, 2026, see the sections entitled "Purchases of Equity Securities by the Issuer and Affiliated Purchasers" in Part II, Item 5 of our Annual Report on Form 10-K and "Issuer Purchases of Equity Securities" in Part II, Item 2 of this Quarterly Report on Form 10-Q.

There can be no assurance of any future share repurchases or share repurchase program authorizations by our Board of Directors. The timing and manner of any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, results of operations and financial condition, alternative investment opportunities, restrictions under any of our agreements, business economic and market conditions, corporate and regulatory requirements, the price of our common stock on the Nasdaq Capital Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our common stock at favorable prices, if at all.

Repurchases pursuant to our share repurchase program could affect our stock price and increase its volatility or diminish our cash reserves, which may impact our ability to finance our future operations. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our common stock. There can be no assurance that any repurchases will enhance shareholder value, because the market price of our common stock may decline below the levels at which we repurchased our common stock. Although our share repurchase program is intended to enhance long-term shareholder value, short-term stock price fluctuations could reduce the share repurchase program's effectiveness.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

ISSUER PURCHASES OF EQUITY SECURITIES				
Period	**(a)** **Total Number of Shares (or Units) Purchased**	**(b)** **Average Price Paid per Share (or Unit)**	**(c)** **Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs**	**(d)** **Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs(1)(2)**
July 2026 (July 1 to July 31, 2026)	—	—	—	$200,008,004
August 2026 (August 1 to August 31, 2026)	2,023,452	$49.43	2,023,452	$100,009,534
September 2026 (September 1 to September 30, 2026)	—	—	—	$100,009,534
Total	2,023,452	$49.43	2,023,452	$100,009,534

(1) Transaction fees are excluded.
(2) We repurchased approximately $100 million of the Company's shares of common stock under the program during the third quarter of fiscal year 2026.

On September 3, 2025, the Company announced that its Board of Directors had authorized and approved the 2025 Share Repurchase Program for up to $100 million of the currently outstanding shares of the Company's common stock.

On March 18, 2026, the Company announced that its Board of Directors had authorized and approved an increase to the 2025 Share Repurchase Program from $100 million to $300 million of the currently outstanding shares of the Company's common stock.

Repurchases under the 2025 Share Repurchase Program may be made using open market purchases, privately negotiated transactions, block purchases or other methods in accordance with applicable federal securities laws, including Rule 10b-18 of the Exchange Act. The 2025 Share Repurchase Program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any particular amount of our common stock.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Securities Trading Plans of Directors and Executive Officers

During the three months ended September 30, 2026, none of our directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of the Company's securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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 9, 2026.
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 9, 2026.
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 9, 2026.
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 9, 2026.
101*	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, 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).

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* 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 9, 2026

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 9, 2026

/s/ Michael S. Weiss

Michael S. Weiss
Chairman, Chief Executive Officer and President

Exhibit 31.2

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

I, Sean A. Power, certify that:

1. I have reviewed this 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 9, 2026

/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, 2026 as filed with the Securities and Exchange Commission (the Report), I, Michael S. Weiss, Chairman, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: November 9, 2026

/s/ Michael S. Weiss

Michael S. Weiss
Chairman, Chief Executive Officer and President

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF

TG THERAPEUTICS, INC.

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the Company) on Form 10-Q for the period ended September 30, 2026 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 9, 2026

/s/ Sean A. Power

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