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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, 2024

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
(Registrants telephone number, including area code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

There were 155,665,334 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 4, 2024.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED September 30, 2024

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to obtain and maintain regulatory approvals for our product candidates, including azercabtagene zapreleucel (azer-cel), and our ability to maintain regulatory approval of BRIUMVI® (ublituximab) for the treatment of relapsing forms of multiple sclerosis (RMS) or any other future indication in the United States (U.S.), the European Union (EU) and the United Kingdom (UK);
- our ability to adapt and expand our commercial infrastructure to successfully launch, market and sell BRIUMVI and our other product candidates;
- our ability to maintain a reliable supply of our products that meets market demand;
- the success of the ongoing commercialization of BRIUMVI or any future products or combinations of products, including the anticipated rate and degree of market acceptance and pricing and reimbursement;
- the initiation, timing, progress and results of our 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 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;
- 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.

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risks, the risk factors in Item 1A, and 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 we are unable to maintain current approval of BRIUMVI, our business will be materially harmed.
- We cannot predict when or if we will obtain regulatory approval to commercialize our product candidates, including azer-cel in non-oncology indications.
- We have limited experience operating as a commercial company, and, as a result, the marketing and sale of BRIUMVI for the treatment of RMS may be less successful than anticipated.
- If BRIUMVI or any of our future product candidates (if approved) do not achieve broad market acceptance among physicians, patients, payors or the medical community, the revenues that we generate from product sales will be limited.
- If the market opportunities for BRIUMVI and any future products for which we may receive approval, including azer-cel in non-oncology indications, are smaller than we estimate or if any approval we obtain is based on a narrower patient population or the labeling includes warnings or limitations that are not acceptable to patients or healthcare providers, our revenue will be adversely affected.
- We face substantial competition for treatments for our target indications, including from companies with greater resources than we have, which may result in others commercializing drugs before or more successfully than we do, which could result in the reduction or elimination of our commercial opportunity.
- If we are unable to generate sufficient revenue, we may need to raise substantial additional capital to sustain our business.
- Product liability lawsuits could cause us to incur substantial liabilities and limit product commercialization.

Risks Related to Drug Development and Regulatory Approval

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

Risks Related to Governmental Regulation of the Pharmaceutical Industry

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

Risks Related to our Dependence on Third Parties

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

Risks Related to Intellectual Property

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

Risks Related to our Financial Position and Need for Additional Capital

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

General Risk Factors

- 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 upon infection. These concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development.
- We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion.
- Our ability to continue our clinical development and commercialization activities will depend on our ability to attract and maintain key management and other personnel.
- Certain of our executive officers, directors and other stockholders own more than 5% of our outstanding common stock and may be able to influence our management and the outcome of matters submitted to shareholders for approval.
- Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition more difficult, which could limit the price investors might be willing to pay for our common stock.
- Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit and could subject us to securities and shareholder derivative litigation.
- Significant disruptions of information technology systems, breaches of data security or unauthorized disclosures of sensitive data could harm our business and subject us to liability or reputational damage.

The foregoing is only a summary of some of our risks. These and other risks are discussed more fully in the section entitled "Risk Factors" in Part 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, 2024 (Unaudited)	December 31, 2023 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 195,822	$ 92,933
Short-term investment securities	145,219	124,575
Accounts receivable, net	115,727	51,093
Inventories	84,669	39,823
Other current assets	32,632	9,519
Total current assets	574,069	317,943
Restricted cash	1,295	1,285
Long-term investment securities	1,125	—
Right of use assets	7,411	8,050
Other noncurrent assets(1)	2,114	2,309
Total assets	$ 586,014	$ 329,587
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 101,407	$ 38,471
Other current liabilities	3,298	1,479
Lease liability – current portion	1,231	1,446
Deferred revenue - current portion	9,093	152
Accrued compensation	10,085	12,172
Total current liabilities	125,114	53,720
Deferred revenue, non-current portion	16,166	6,016
Loan payable – non-current	244,158	100,118
Lease liability – non-current	8,419	9,231
Total liabilities	393,857	169,085
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value per share (190,000,000 and 175,000,000 shares authorized, 155,910,901 and 151,465,598 shares issued, 155,777,291 and 151,424,289 shares outstanding at September 30, 2024 and December 31, 2023, respectively)	156	151
Additional paid-in capital	1,746,909	1,713,162
Treasury stock, at cost, 133,610 and 41,309 shares at September 30, 2024 and December 31, 2023, respectively	(2,383)	(234)
Accumulated deficit	(1,552,525)	(1,552,577)
Total stockholders' equity	192,157	160,502
Total liabilities and stockholders' equity	$ 586,014	$ 329,587

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

(1) Amounts as of December 31, 2023 have been reclassified to conform to current period presentation.

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,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 83,297	$ 25,068	$ 206,381	$ 48,868
License, milestone, royalty and other revenue	582	140,747	14,438	140,823
Total revenue	$ 83,879	$ 165,815	$ 220,819	$ 189,691
Costs and expenses:				
Cost of revenue	9,341	3,509	23,087	6,277
Research and development:				
Noncash compensation	3,028	2,915	8,000	10,162
Other research and development	17,110	11,838	62,417	48,581
Total research and development	20,138	14,753	70,417	58,743
Selling, general and administrative:				
Noncash compensation	8,745	6,269	$ 22,593	18,386
Other selling, general and administrative	33,221	26,500	$ 92,742	73,167
Total selling, general and administrative	41,966	32,769	115,335	91,553
Total costs and expenses	71,445	51,031	208,839	156,573
Operating income	12,434	114,784	11,980	33,118
Other expense (income):				
Interest expense	10,832	3,713	$ 16,967	10,184
Other income	(2,666)	(2,859)	$ (5,128)	(4,154)
Total other expense, net	8,166	854	11,839	6,030
Net income before taxes	$ 4,268	$ 113,930	$ 141	$ 27,088
Income tax expense	$ 388	—	$ 89	—
Net income	$ 3,880	$ 113,930	$ 52	$ 27,088
Net income per common share:				
Basic	$ 0.03	$ 0.80	$ 0.00	$ 0.19
Diluted	$ 0.02	$ 0.73	$ 0.00	$ 0.19
Weighted-average shares of common stock outstanding				
Basic	145,102,479	142,871,227	145,342,337	141,571,785
Diluted	160,714,388	155,871,749	160,366,927	145,952,913

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	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2023	146,426,697	$ 146	$1,623,924	41,309	$ (234)	$ (1,565,249)	$ 58,587
Issuance of common stock in connection with exercise of options	66,701	*	363	—	—	—	363
Issuance of restricted stock	3,017,736	3	(3)	—	—	—	—
Warrants issued with debt financing	—	—	595	—	—	—	595
Forfeiture of restricted stock	(73,787)	*	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	7,120	—	—	—	7,120
Net loss	—	—	—	—	—	(39,232)	(39,232)
Balance at March 31, 2023	149,437,347	149	1,631,999	41,309	(234)	(1,604,481)	27,433
Issuance of common stock in connection with exercise of options	76,955	*	751	—	—	—	751
Issuance of restricted stock	95,000	*	*	—	—	—	—
Forfeiture of restricted stock	(25,679)	*	*	—	—	—	—
Issuance of common stock in public offering (net of offering costs of $0.8 million)	1,385,700	2	46,295				46,297
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	13,582	—	—	—	13,582
Net loss	—	—	—	—	—	(47,610)	(47,610)
Balance at June 30, 2023	150,969,323	151	1,692,627	41,309	(234)	(1,652,091)	40,453
Issuance of common stock in connection with exercise of options	102,500	*	420	—	—	—	420
Issuance of restricted stock	457,501	*	*	—	—	—	—
Forfeiture of restricted stock	(38,593)	*	*	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	9,966	—	—	—	9,966
Net loss	—	—	—	—	—	113,930	113,930
Balance at September 30, 2023	151,490,731	151	1,703,013	41,309	(234)	(1,538,161)	164,769

	Common Stock		Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2024	151,465,598	$ 151	$1,713,162	41,309	$ (234)	$ (1,552,577)	$ 160,502
Issuance of common stock in connection with exercise of options	2,500	*	10	—	—	—	10
Issuance of restricted stock	3,304,468	4	(4)	—	—	—	—
Forfeiture of restricted stock	(165,514)	*	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	10,304	—	—	—	10,304
Net loss	—	—		—	—	(10,707)	(10,707)
Balance at March 31, 2024	154,607,052	155	1,723,472	41,309	(234)	(1,563,284)	160,109
Issuance of common stock in connection with exercise of options	27,250	*	135	—	—	—	135
Issuance of restricted stock	332,138	*	—	—	—	—	—
Forfeiture of restricted stock	(92,593)	*	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	10,445	—	—	—	10,445
Net income	—	—		—	—	6,879	6,879
Balance at June 30, 2024	154,873,847	155	1,734,052	41,309	(234)	(1,556,405)	177,568
Issuance of common stock in connection with exercise of options	35,313	*	199	—	—	—	199
Issuance of restricted stock	1,038,407	1	(1)	—	—	—	—
Forfeiture of restricted stock	(36,666)	*	*	—	—	—	—
Repurchase of common stock	—	—	—	92,301	(2,149)	—	(2,149)
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	12,659	—	—	—	12,659
Net income	—	—	—	—	—	3,880	3,880
Balance at September 30, 2024	155,910,901	156	1,746,909	133,610	(2,383)	(1,552,525)	192,157

**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,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 52	$ 27,088
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt	4,607	0
Noncash stock compensation expense	30,593	28,548
Depreciation and amortization	59	173
Amortization of premium (discount) on investment securities	(5,287)	(704)
Amortization of debt issuance costs	1,692	1,739
Amortization of leasehold interest	159	159
Noncash change in lease liability and right of use asset	1,402	1,473
Change in fair value of equity investments	253	—
Change in fair value of notes payable	151	(71)
Changes in assets and liabilities:		
Increase in inventory	(42,031)	(31,432)
Increase in other current assets	(23,047)	(10,365)
Increase in accounts receivable	(64,634)	(39,320)
Increase (decrease) in accounts payable and accrued expenses	60,850	(2,372)
Decrease in lease liabilities	(1,790)	(1,780)
Increase in other current liabilities	2,851	2,024
Increase in deferred revenue	19,244	6,637
Net cash used in operating activities	(14,876)	(18,203)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of short-term securities	237,200	72,551
Investment in held-to-maturity securities	(252,625)	(78,447)
Investment in long-term securities	(1,375)	—
Purchases of Property, Plant and Equipment	(24)	—
Net cash used in investing activities	(16,824)	(5,896)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of loan payable	(107,553)	—
Issuance of common stock, net	—	46,297
Proceeds from exercise of options	344	1,534
Proceeds from debt financings	244,815	25,000
Financing costs paid	(858)	(125)
Purchase of treasury stock	(2,149)	—
Net cash provided by financing activities	134,599	72,706
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	102,899	48,607
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	94,218	103,577
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 197,117	$ 152,184
Reconciliation to amounts on condensed consolidated balance sheets:		
Cash and cash equivalents	$ 195,822	$ 150,902
Restricted cash	1,295	1,282
Total cash, cash equivalents and restricted cash	$ 197,117	$ 152,184
Cash paid for:		
Interest	$ 12,048	$ 3,929
NONCASH TRANSACTIONS		
Deferred financing costs	$ —	$ 1,238
Warrants issued with debt financing	$ —	$ 595

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

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Basis of Presentation

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (GAAP), for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2023. The accompanying condensed balance sheet as of December 31, 2023 has been derived from these statements. The results of operations for the three and nine months ended September 30, 2024 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

Historically, we have incurred operating losses; however, during the three and nine months ended September 30, 2024, the Company generated net income. Additionally, during the twelve months ended December 31, 2023, the Company experienced a net profit due to a $ 140.0 million non-refundable upfront payment recognized as license revenue in the third quarter of 2023 as part of our ex-U.S. commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm) (see Note 2 for more information). We may incur operating losses in the near term and may never become profitable. As of September 30, 2024, we have an accumulated deficit of $ 1.6 billion.

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, from our loan and security agreements, the upfront payment from the Commercialization Agreement (see Note 2 for more information), and from product revenue from drug sales of BRIUMVI. During the nine months ended September 30, 2024, we generated $ 206.4 million in product revenue from drug sales of BRIUMVI. BRIUMVI is currently our only marketed product. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. We expect to continue to incur significant research and development expenses, as well as significant commercialization and outsourced manufacturing expenses as we continue to commercialize BRIUMVI. 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 a net profit. We may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

As of September 30, 2024, we had $ 341.0 million in cash and cash equivalents, and investment securities. The Company believes its existing cash, cash equivalents, and investment securities, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will be sufficient to fund our anticipated operating cash requirements for at least twelve months following the date of this filing.

The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, our commercialization efforts for BRIUMVI, preparations for the potential commercialization of our other drug candidates, and the timing, design and conduct of clinical trials for our drug candidates as well as the costs associated with licensing or otherwise acquiring new product candidates. We may be dependent upon significant future financing to provide the cash necessary to execute our ongoing and future operations, including the commercialization of any of our drug candidates.

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

Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, except as updated herein or as it relates to revenue recognition, accounts receivable, inventory, cost of revenue, equity securities, and the adoption of new accounting standards during the nine months ended September 30, 2024. 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.

Financial Statement Reclassification

Certain account balances from prior periods have been reclassified in these financial statements to conform to current period classifications.

Revenue Recognition

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

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

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

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

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

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 also receives sales order management, inventory management, and data services from its customers in exchange for certain fees.

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

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

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

As of September 30, 2024, the Company has not received any returns related to sales of BRIUMVI.

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

License Agreements

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

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

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

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

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

Other Revenue

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

Deferred Product Revenue

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

Accounts Receivable

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns and chargebacks. Our contracts with customers have standard payment terms. We analyze accounts that are past due for collectability, and regularly evaluate the creditworthiness of our customers so that we can properly assess and respond to changes in their credit profiles. As of September 30, 2024, we determined an allowance for expected credit losses related to outstanding accounts receivable was currently not required based upon our review of contractual payment terms and individual customer circumstances.

Cost of Revenue

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

Inventory

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in-first-out method (FIFO). The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, if they occur, are recorded within cost of revenue.

Prior to regulatory approval, we expense costs relating to the production of inventory as research and development expense in the period incurred. Following regulatory approval, costs to manufacture those approved products will be capitalized. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Equity Securities

Our equity securities consist of common stock of Precision BioSciences, Inc. (Precision). 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 for further details.

Net Income (Loss) Per Common Share

Basic net income (loss) per share of our common stock is calculated by dividing net income (loss) applicable to the common stock by the weighted-average number of shares of our common stock outstanding for the period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options, and restricted stock, which would result in the issuance of incremental shares of common stock. The impact of these items is anti-dilutive during periods of net loss. Therefore, basic and diluted net income (loss) per share would be the same for all periods presented. However, for the three and nine months ended September 30, 2024 and 2023, the Company had net income in the unaudited condensed consolidated statement of operations.

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The following table summarizes our potentially dilutive securities at September 30, 2024 and 2023:

	As of September 30,	
	2024	**2023**
Unvested restricted stock	10,645,967	8,454,545
Options	4,631,966	4,697,029
Warrants	312,272	312,272
Shares issuable upon note conversion	21,704	20,646
Total	15,611,909	13,484,492

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)	**2024**	**2023**	**2024**	**2023**
Net income (loss)	3,880	113,930	52	27,088
Weighted-average common shares outstanding	145,102,479	142,871,227	145,342,337	141,571,785
Dilutive effect of potential common shares	15,611,909	13,000,522	15,024,590	4,381,128
Weighted-average common shares outstanding assuming dilution	160,714,388	155,871,749	160,366,927	145,952,913
Net income (loss) per share - basic	0.03	0.80	0.00	0.19
Net income (loss) per share - diluted	0.02	0.73	0.00	0.19

NOTE 2 REVENUE

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

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Total product revenue, net	$ 83,297	$ 25,068	$ 206,381	$ 48,868
License Revenue	38	140,038	114	140,114
Milestone Revenue	—	—	12,500	—
Royalty Revenue	229	—	412	—
Other Revenue	315	709	1,412	709
Total Revenue	$ 83,879	$ 165,815	$ 220,819	$ 189,691

Product revenue, net

For the three and nine months ended September 30, 2024, our only source of product revenue has been from U.S. sales of BRIUMVI, which we began shipping to our customers in January 2023.

As of September 30, 2024, approximately $ 24.4 million of gross-to-net accruals are included within accounts receivable, net, accounts payable and accrued expenses on the condensed consolidated balance sheets.

License Agreements

Neuraxpharm Commercialization Agreement

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

In consideration for entering into the Commercialization Agreement, the Company received a non-refundable upfront payment of $ 140.0 million. The Company will also receive tiered double-digit royalties up to 30 % on net product sales in the Territory and is eligible to receive sales-based or other milestone payments totaling up to $ 492.5 million.

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

The License to the Company's intellectual property represents a distinct performance obligation, therefore, the $ 140.0 million non-refundable upfront payment related to this performance obligation was recognized as License Revenue in the third quarter of 2023.

The Development and Regulatory Activities performance obligation is satisfied over time because Neuraxpharm simultaneously receives and consumes the benefits provided by the Company's performance of the services. Therefore, revenue is recognized as the activities are completed by the Company. For the three and nine months ended September 30, 2024, the Company recognized Other Revenue of $ 0.3 million and $ 1.4 million, respectively, related to the Development and Regulatory Activities.

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

The performance obligation related to the Supply of Licensed Product is met when control of the product passes to Neuraxpharm. The consideration received from Neuraxpharm for the supply of BRIUMVI will be recognized by the Company as a component of product revenue, net. As of September 30, 2024, the Company has an unconditional right to receive $ 18.3 million in consideration from Neuraxpharm related to the performance obligation to supply BRIUMVI, that is recorded as accounts receivable, net. The related performance obligation to supply BRIUMVI has not yet been satisfied, and therefore, as of September 30, 2024, $ 25.2 million has been recorded as deferred revenue. The Company will reevaluate the consideration received, and performance obligations satisfied, at the end of each reporting period. Such reevaluations may result in a change to the amount of product revenue, net, recognized and deferred revenue.

The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are highly dependent on factors outside of the Company's control. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue in the period when the related sales threshold is met. All other milestones will be recognized as revenue immediately in the period the achievement of the underlying milestone is probable. In March 2024, the Company received a $ 12.5 million milestone payment for the first key market commercial launch of BRIUMVI in the EU. Any consideration related to sales-based royalties will be recognized when the related sales occur. During the three and nine months ended September 30, 2024, royalty revenue of $ 0.2 million and $ 0.4 million, respectively, was recognized.

NOTE 3 INVESTMENT SECURITIES

Our short-term investments as of September 30, 2024 and December 31, 2023 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our short-term investment securities at September 30, 2024 and December 31, 2023:

	September 30, 2024			
(in thousands)	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between October 2024 and March 2025) (held-to-maturity)	$ 145,219	$ 122	$ 3	$ 145,338
Total short-term investments	$ 145,219	$ 122	$ 3	$ 145,338

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

Our long-term investments as of September 30, 2024 include shares of common stock of Precision. The fair market value of the equity securities as of September 30, 2024 was $ 0.9 million. For the three and nine months ended September 30, 2024, we recorded unrealized losses of $ 0.1 million and $ 0.3 million, respectively, based on the change in fair value of Precision's common stock during the period. See Note 5 for further details.

NOTE 4 INVENTORY

The following table presents our inventory as of September 30, 2024 (in thousands):

	September 30, 2024
Raw Materials	$ 1,734
Work in Process	74,973
Finished Goods	7,962
Total Inventory	$ 84,669

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 expense when consumed.

At September 30, 2024, all our inventory was solely related to BRIUMVI, which was approved by the FDA on December 28, 2022, at which time we began to capitalize costs to manufacture BRIUMVI. Prior to the FDA approval of BRIUMVI, all costs related to the manufacturing of BRIUMVI and related material were charged to research and development expense in the period incurred.

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. Our expectation is to sell finished goods at least twelve months prior to expiration. Due to our long manufacturing lead time, it was necessary to buildup inventory in support of BRIUMVI forecasted sales, to ensure appropriate safety stock levels, and meet our commitment to supply BRIUMVI to Neuraxpharm related to the Commercialization Agreement. As a result of being in the early stages of the BRIUMVI product launch, the Company is continuing to evaluate the length of its operating cycle.

On a quarterly basis, the Company analyzes our inventory levels for excess quantities and obsolescence (expiration), taking into account factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf-life. At September 30, 2024, we determined that a reserve related to BRIUMVI inventory for excess quantities and obsolescence is not required. In addition, since FDA approval of BRIUMVI, the Company has not recorded any inventory write downs.

NOTE 5 FAIR VALUE MEASUREMENTS

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

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

Equity Investments and Forward Contract Liabilities

On January 7, 2024, (the Precision Effective Date) the Company and its wholly-owned subsidiary, TG Cell Therapy, Inc., (TG Cell) entered into a License Agreement (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 (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 had a 30 -to-1 reverse stock split in February 2024. The shares purchased with the Upfront Precision Stock Payment are classified as an equity investment and are recognized at fair market value as of September 30, 2024.

Within 12 months following the Precision Effective Date, the Company will make a one-time payment to Precision equal to $ 2.5 million (the Deferred Precision Stock Payment). Upon receipt of such payment, Precision shall issue to the Company the number of shares of Precision common stock (the Precision Shares) (rounded down to the nearest whole share) obtained by dividing the Deferred Precision Stock Payment by 200 % of the weighted average share price of the Precision common stock (the Precision Share Price) for the thirty (30) trading days preceding the date on which Precision receives the payment. The Deferred Precision Stock Payment was recorded to research and development License Fees as part of the cost of the Precision License Agreement in the three months ended March 31, 2024, and is classified as a forward contract liability recognized at fair market value in Other Current Liabilities as of September 30, 2024 , in accordance with ASC 321.

Upon the achievement of a clinical and regulatory milestone event (Milestone Event 1), the Company will make a one-time payment to Precision equal to $ 2.3 million (the Milestone 1 Precision Stock Payment). Upon receipt of such payment, Precision shall issue to the Company the Precision Shares (rounded down to the nearest whole share) obtained by dividing the Milestone 1 Precision Stock Payment by 200 % of the weighted average share price of the Precision common stock (the Precision Share Price) for the thirty (30) trading days preceding the achievement of Milestone Event 1. The Milestone 1 Precision Stock Payment was recorded to research and development License Fees as part of the cost of the Precision License Agreement in the three months ended March 31, 2024, and is classified as a forward contract liability recognized at fair market value in Other Current Liabilities as of September 30, 2024 , in accordance with ASC 321.

5% Notes

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

The Company's financial instruments include cash, cash equivalents consisting of money market funds, accounts receivable, accounts payable and loan payable. As of September 30, 2024 and December 31, 2023, the fair values of cash and cash equivalents, restricted cash, accounts receivable, and loan and interest payable approximate their carrying value. The carrying value of loan payable on the Company's balance sheet is estimated to approximate its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics.

The following tables provide the fair value measurements of applicable financial assets and liabilities as of September 30, 2024 and December 31, 2023:

(in thousands)	Financial assets and liabilities at fair value as of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Equity Investments	$ 872	$ —	$ —	$ 872
Total Assets	$ 872	$ —	$ —	$ 872
Forward Contract Liabilities	$ —	$ 2,568	$ —	$ 2,568
5% Notes	$ —	$ —	$ 508	$ 508
Total Liabilities	$ —	$ 2,568	$ 508	$ 3,076

	Financial assets and liabilities at fair value as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
5% Notes	$ —	$ —	$ 357	$ 357
Total Liabilities	$ —	$ —	$ 357	$ 357

Our equity investments classified as Level 1 were valued using their respective closing stock price on the Nasdaq Stock Market. We did not experience any transfers of financial instruments between the fair value hierarchy levels during the three months ended September 30, 2024. Our forward contract liabilities classified as Level 2 were valued using Precision's closing stock price on the Nasdaq Stock Market. Our Level 3 instrument amounts represent the fair value of the 5% Notes and related accrued interest.

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

NOTE 6 STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

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

During the six months ended June 30, 2023, we sold a total of 1,385,700 shares of common stock under the 2022 ATM for aggregate total gross proceeds of approximately $ 47.1 million at an average selling price of $ 34.01 per share, resulting in net proceeds of approximately $ 46.3 million after deducting commissions and other transactions costs. We had no activity on the 2022 ATM during the nine months ended September 30, 2024. The 2022 WKSI Shelf is currently our only active shelf registration statement. We may offer any combination of the securities registered under the 2022 WKSI Shelf from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We may need to file additional shelf registration statements in the future to provide us with the flexibility to raise additional capital to finance our operations as needed.

Share Repurchase Program and Treasury Stock

On August 2, 2024, the Company announced that its Board of Directors (the Board) had authorized and approved a share repurchase program for up to $ 100 million of the currently outstanding shares of the Company's common stock. Under the share repurchase program, the Company intends to repurchase shares through open market purchases, privately-negotiated transactions, block purchases or other methods in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934, as amended (the Exchange Act). For the three months ended September 30, 2024, the Company repurchased 92,301 shares of common stock at a cost of $ 2.1 million. As of September 30, 2024, 133,610 shares of common stock are being held in Treasury, at a cost of approximately $ 2.4 million, representing the fair market value on the date the shares were surrendered to the Company, mainly as part of our share repurchase program.

Equity Incentive Plans

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. As of September 30, 2024, 8,231,871 shares of restricted stock and 2,267,500 options were outstanding and up to an additional 4,314,901 shares were available to be issued under the 2022 Incentive Plan.

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (the 2012 Incentive Plan) was approved by stockholders in June 2020. As of September 30, 2024, 3,914,127 shares of restricted stock and 2,364,466 options were outstanding, and no additional shares were available to be issued under the 2012 Incentive Plan as the 2022 Incentive Plan is currently the Company's only active incentive plan.

Stock-based compensation expense included in the condensed consolidated statements of operations was $ 11.8 million and $ 9.2 million for the three months ended September 30, 2024, and 2023, respectively, and $ 30.6 million and $ 28.5 million for the nine months ended September 30, 2024 and 2023, respectively. Stock-based compensation expense of $ 11.8 million and the $ 30.6 million for the three and nine months ended September 30, 2024, respectively, is net of $ 0.9 million and $ 2.8 million of stock-based compensation expense that was capitalized into inventory, respectively.

During July of 2024, the Company identified an error related to the expense recognition of a single restricted stock award granted in 2021. The impact of the error was an understatement of non-cash compensation expense (SG&A) in the years ended December 31, 2022, and 2021 and a corresponding understatement of additional paid in capital (APIC). The Company has concluded the error did not result in a material misstatement of the Company's previously issued consolidated financial statements. The cumulative impact of the error has been corrected as an immaterial correction of the December 31, 2023 condensed consolidated balance sheet by increasing accumulated deficit and APIC by approximately $ 38.2 million.

Stock Options and Restricted Stock

The following table summarizes the activity for stock options and restricted stock for the nine months ended September 30, 2024:

	Stock Options	Restricted Stock
Equity awards outstanding, beginning of year	4,697,029	9,639,068
Changes during the year:		
Granted	—	4,675,013
Exercised or vested	(65,063)	(1,873,310)
Expired or Forfeited	—	(294,773)
Equity awards outstanding, end of period	4,631,966	12,145,998

As of September 30, 2024, total compensation cost related to unvested time-based awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized were as follows:

(in thousands)	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 2,025	$ 42,737
Expected weighted-average period in years of compensation cost to be recognized	1.8	2.9

As of September 30, 2024, total compensation cost related to unvested market-based awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized were as follows:

(in thousands)	Restricted Stock
Unrecognized compensation cost	$ 31,204
Expected weighted-average period in years of compensation cost to be recognized	3.8

Warrants

The Company's only outstanding warrants are warrants issued to Hercules as part of the prior loan agreements to purchase 147,058 , 115,042 and 50,172 shares of our common stock with exercise prices of $ 4.08 , $ 17.95 and $ 14.70 , respectively. The First Amendment (as defined below) contained warrant coverage of 2.95 % of each advance amount funded. A warrant was issued by the Company to Hercules to purchase 50,172 shares of common stock with an exercise price of $ 14.70 (the First Amendment Warrant). The First Amendment Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the First Amendment Warrant either by (a) cash or check or (b) through a net issuance conversion. There will not be any ongoing stock compensation expense associated with these warrants.

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

	Amended Term Loan
Exercise price	$ 14.70
Common share price on date of issuance	$ 15.04
Volatility	0.88%
Risk-free interest rate	3.6%
Expected dividend yield	—
Contractual term (in years)	7.00

NOTE 7 LOAN PAYABLE

On March 31, 2023, the Company entered into a First Amendment to the Amended Loan Agreement (the First Amendment) with Hercules Capital, Inc. (Hercules). The First Amendment amended the terms of the Amended and Restated Loan and Security Agreement (Amended Loan Agreement) with Hercules that closed on December 30, 2021.

On August 2, 2024 (the New 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 and Blue Owl Capital under the Financing Agreement (as defined below). The Company repaid all outstanding principal and accrued interest and fees under the First Amendment with Hercules (such repayment, the Refinancing), which Refinancing was funded with the proceeds of the Initial Term Loan. The existing Amended Loan Agreement with Hercules was effectively terminated, and all guarantees and liens granted thereunder were released upon the consummation of the Refinancing.

The Initial Term Loan is governed by a financing agreement, dated as of the New Closing Date (the Financing Agreement), which provides for (i) a single draw of the Initial Term Loan on the New Closing Date 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) at 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, plus 1.00 % or (b) Term SOFR, which, shall be no less than 1.00 %. The applicable margin for borrowings of the Initial Term Loan is determined on a quarterly basis by reference to a pricing grid based on the achievement of US Net Sales (as defined in the Financing Agreement) for the most recently completed four consecutive fiscal quarters of the Company and its Subsidiaries (as defined in the Financing Agreement). The pricing grid commences at 5.50 % for SOFR borrowings and 4.50 % for base rate borrowings and is subject to a 25 basis point step-down upon achievement of a specified US Net Sales threshold. The Initial Term Loan requires scheduled quarterly amortization payments, commencing with the fiscal quarter ending June 30, 2028, in an amount equal to $ 12.5 million, with the balance due and payable on the Term Loan Maturity Date; provided that such amortization payments may be deferred to the Term Loan Maturity Date upon the achievement of a Total Net Leverage Ratio (as defined in the Financing Agreement) that is less than or equal to an agreed threshold.

The Initial 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.

The events of default under the Financing Agreement are customary for financings of this type. If an event of default occurs, the Administrative Agent is entitled to take enforcement action, including acceleration of amounts due under the Financing Agreement.

The Company evaluated whether the Initial Term Loan represented a debt modification or extinguishment of the First Amendment with Hercules with ASC 470-50, Debt – Modifications and Extinguishments. As a result of the Initial Term Loan and effective termination of the First Amendment with Hercules, this transaction was accounted for by the Company under the extinguishment accounting model. The Company recorded a loss on extinguishment of debt of approximately $ 4.6 million in the Company's statement of operations for the three and nine months ended September 30, 2024, representing the write-off of unamortized debt issuance costs and a prepayment charge. The Company capitalized third party fees from the Initial Term Loan to debt issuance costs and capitalized the facility fee incurred with the Administrative Agent as part of the Initial Term Loan to debt discount.

The Company incurred total financing and upfront costs of $ 6.0 million related to the Initial 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, which approximates the effective interest method, and will be included in interest expense in the Company's consolidated statements of operations. Amortization of debt issuance and debt discount costs was $ 4.0 million (including write off of remaining debt issuance balance under the First Amendment with Hercules) and $ 0.6 million for the three months ended September 30, 2024, and 2023, respectively, and $ 5.3 million (including a write off of remaining debt issuance balance under the First Amendment with Hercules) and $ 1.7 million for the nine months ended September 30, 2024 and 2023, respectively. At September 30, 2024, the remaining unamortized balance of debt issuance and debt discount costs was $ 5.8 million.

The loan payable balance of the First Amendment as of September 30, 2024 and December 31, 2023 is as follows:

	The First Amendment	
(in thousands)	September 30, 2024	December 31, 2023
Loan payable	$ 95,000	$ 95,000
Add: Accreted Liability of final payment fee	12,553	10,230
	107,553	105,230
Less: unamortized debt issuance and debt discount costs		(5,112)
	107,553	100,118
Less: principal payments	(107,553)	—
Total loan payable	—	100,118
Less: current portion	—	—
Loan payable non-current	$ —	$ 100,118

The loan payable balance of the Initial Term Loan as of September 30, 2024, is as follows:

	The Initial Term Loan
(in thousands)	September 30, 2024
Loan payable	$ 250,000
Add: Accreted Liability of final payment fee	—
	250,000
Less: unamortized debt issuance and debt discount costs	(5,842)
	244,158
Less: principal payments	—
Total loan payable	244,158
Less: current portion	—
Loan payable non-current	$ 244,158

NOTE 8 LEASES

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

In October 2019, we finalized a five-year lease for office space in New Jersey (the NJ Lease). We approximate an average annual rental obligation of $ 0.3 million under the NJ Lease. We took possession of this space in October 2019, with rental payments beginning in November 2019. We incurred rental expense of $ 0.2 million for the nine months ended September 30, 2024.

In October 2021, we finalized a five-year lease for office space in North Carolina (the NC Lease). We approximate an average annual rental obligation of $ 0.2 million under the NC Lease. We took possession of this space in February 2022, with rental payments beginning in April 2022. We incurred rental expense of $ 0.2 million for the nine months ended September 30, 2024.

At January 1, 2019, we recognized a lease liability and corresponding Right-of-Use (ROU) asset of $ 9.5 million and $ 8.1 million, respectively, based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. The present values of our lease liability and corresponding ROU asset are $ 9.7 million and $ 7.4 million, respectively, as of September 30, 2024. Our leases have remaining lease terms of four months to seven years. One lease has a renewal option to extend the lease for an additional term of two years. The following components of lease expense are included in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023:

	Three months ended		Nine months ended	
(in thousands)	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Operating lease cost	$ 551	$ 535	$ 1,702	$ 1,632
Net lease cost	$ 551	$ 535	$ 1,702	$ 1,632

As of September 30, 2024, the weighted-average remaining operating lease term was 5.5 years and the weighted-average discount rate for operating leases was 10.03 %. Cash paid for amounts included in the measurement of operating lease liabilities during the nine months ended September 30, 2024 was $ 1.8 million. The balance sheet classification of lease liabilities was as follows:

(in thousands)	September 30, 2024	December 31, 2023
Liabilities		
Lease liability current portion	$ 1,231	$ 1,446
Lease liability non-current	8,419	9,231
Total lease liability	$ 9,650	$ 10,677

As of September 30, 2024, the maturities of lease liabilities were as follows:

(in thousands)	Operating leases
Remainder of 2024	$ 598
2025	2,100
2026	2,080
2027	1,913
2028	1,827
After 2029	4,715
Total lease payments	13,233
Less: interest	(3,583)
Present value of lease liabilities(*)	$ 9,650

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

NOTE 9 LICENSE AGREEMENTS

BRIUMVI (Ublituximab)

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the LFB License Agreement). Under the terms of the LFB License Agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. As of September 30, 2024, we have incurred approximately $ 31.0 million in expense related to the achievement of certain milestones of 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, 2024, the Company recorded $ 8.3 million and $ 20.4 million, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of revenue based on sales of BRIUMVI in the U.S. and the EU, compared to $ 2.4 million and $ 4.8 million during the three and nine months ended September 30, 2023, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of revenue based on U.S. sales of BRIUMVI. As of September 30, 2024, $ 8.3 million in royalties were payable under the LFB License Agreement.

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

An upfront payment of $ 2.0 million, which was received in December 2012, net of $ 0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or fifteen years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately $ 38,000 for each of the three months ended September 30, 2024 and 2023. At September 30, 2024 and December 31, 2023, we have deferred revenue of approximately $ 0.2 million and $ 0.3 million, respectively, associated with this $ 2 million payment (approximately $ 0.2 million of which has been classified in current liabilities at September 30, 2024 and December 31, 2023).

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

In July 2023, the Company entered into the Commercialization Agreement with Neuraxpharm. The Company granted Neuraxpharm the exclusive right to commercialize BRIUMVI in territories outside the United States, Canada, and Mexico, which are retained by TG, and excluding certain Asian countries previously partnered. Under the terms of the Commercialization Agreement, the Company received a one-time, non-refundable payment of $ 140.0 million upon contract execution (please refer to Note 2 – Revenue). In March 2024, the Company received 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 $ 492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. In addition, TG will receive tiered double-digit royalties on net product sales up to 30 %. Royalty revenue of $ 0.2 million and $ 0.4 million was recognized during the three and nine months ended September 30, 2024, respectively. In the event of a change of control of the Company (as defined in the Commercialization Agreement), the Company retains an option to buy back all rights under the Commercialization Agreement for a period of two years thereafter.

Azer-cel

On January 7, 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 at a price of $ 0.77 per share. Within 12 months of the Precision License Agreement, the Company will make a deferred payment of $ 2.5 million to Precision, consisting of an equity investment in Precision's common stock at a 100 % premium to the 30 -day volume-weighted average price (the 30-day VWAP) prior to purchase. Upon achievement of certain near-term clinical or time-based milestones, the Company will make a $ 7.5 million payment to Precision, a portion of which will also be an equity investment in Precision's common stock at a 100 % premium to the 30 -day VWAP prior to purchase. Precision will be eligible to receive up to $ 288 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity, and a period of ten years following the first commercial sale of the licensed product in such country. The Company has also agreed to make certain payments to Precision's licensors during the term of the Precision License Agreement.

NOTE 10 RELATED PARTY TRANSACTIONS

In July 2015, we entered into a Shared Services Agreement (the Shared Services Agreement) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. The Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately $ 1.1 million and $ 0.7 million for the nine months ended September 30, 2024 and 2023, respectively, primarily related to shared personnel. Mr. Weiss, our Chairman and Chief Executive Officer, also serves as a director and Executive Vice Chairman, Strategic Development of FBIO.

Please refer to Note 8 – Leases for details regarding the Office Agreement with FBIO.

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

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

You should read the following discussion and analysis in conjunction with the unaudited condensed consolidated financial statements and the related footnotes thereto appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023.

OVERVIEW

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

Recent Business Update Highlights

BRIUMVI Five-Year Data Update

In September 2024 we presented new five-year data from the ULTIMATE I & II Phase 3 trials evaluating BRIUMVI® (ublituximab-xiiy) in patients with RMS, at the 2024 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meeting. These data demonstrate that 92% of patients with RMS were free from disability progression after five years of BRIUVI treatment, the annualized relapse rate during year five of treatment was 0.02 (equivalent to one relapse occurring every fifty years of patient treatment), and the overall safety profile remained consistent over five years of continuous treatment, with no new safety signals emerging with prolonged treatment.

Ublituximab Development

In August 2024, we announced the initiation of a Phase 1 clinical trial evaluating a subcutaneous formulation of ublituximab in patients with RMS and that patients have been dosed.

Pipeline

In August 2024, we announced FDA clearance of the Investigational New Drug Application (IND) for azercabtagene zapreleucel (azer-cel) for the treatment of progressive forms of multiple sclerosis. Previously, in January 2024, we entered into an agreement with Precision BioSciences, Inc. (Precision) to acquire a worldwide license to Precision's azer-cel, for autoimmune diseases and all other non-oncology indications. Azer-cel is an allogeneic (off the shelf) CAR T program, and the Company has near term plans to evaluate the program in multiple autoimmune indications.

OUR PRODUCTS

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

Clinical Drug Candidate: (molecular target)	**Initial Target Disease**	**Stage/Status of Development**
Ublituximab (anti-CD20 mAb)	Relapsing Forms of Multiple Sclerosis (RMS)	APPROVED
Subcutaneous ublituximab	RMS	Phase 1
Azer-cel	Progressive Forms of Multiple Sclerosis	IND Accepted

BRIUMVI (ublituximab-xiiy) Overview

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

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

- In December 2020, we announced positive topline results from the ULTIMATE I & II trials. Both studies met their primary endpoint of significantly reducing ARR over a 96-week period ($p<0.005$ in each study) with 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 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 August 2024, we announced the initiation of a Phase 1 clinical trial evaluating a subcutaneous formulation of ublituximab in patients with RMS and that the first patients have been dosed.
- Additional data sets from the ULTIMATE I & II Phase 3 trials continue to be presented at major medical meetings, including five year long term data which was presented for the first time at the 2024 ECTRIMS meeting in September, and updated data from the ENHANCE Phase 3b trial evaluating RMS patients who switch from an IV anti-CD20 therapy to BRIUMVI and evaluating a shorter infusion time of as low as 30 minutes for BRIUMVI.

U.S. Commercialization of BRIUMVI

On December 28, 2022, we announced the FDA approval of BRIUMVI for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, primarily based on results from the ULTIMATE I & II Phase 3 trials. On January 26, 2023, we announced the U.S. commercial launch of BRIUMVI, making it available to physicians and patients and the first RMS patient received a BRIUMVI infusion on February 1, 2023.

Ex-U.S. Commercialization of BRIUMVI

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

On August 1, 2023, we announced an agreement with Neuraxpharm 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 (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 of which the Company previously partnered. We retain an option to buy back all rights under the Commercialization Agreement for a period of two years in the event of a change in control of TG.

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

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

For more information, please refer to our Annual Report on Form 10-K for the quarter and year ended December 31, 2023.

RESULTS OF OPERATIONS

The following table summarizes the results of operations for the three months ended September 30, 2024 and 2023:

(in thousands)	Three months ended September 30, 2024	2023
Product revenue, net	$ 83,297	$ 25,068
License, milestone, royalty and other revenue	582	140,747
Total Revenue	$ 83,879	$ 165,815
Costs and expenses:		
Cost of revenue	9,341	3,509
Research and development:		
Noncash compensation	3,028	2,915
Other research and development	17,110	11,838
Total research and development	20,138	14,753
General and administrative:		
Noncash compensation	8,745	6,269
Other selling, general and administrative	33,221	26,500
Total general and administrative	41,966	32,769
Total costs and expenses	71,445	51,031
Interest expense	10,832	3,713
Other income	(2,666)	(2,859)
Total other expense, net	8,166	854
Net income before taxes	4,268	113,930
Income tax expense	388	—
Net income	$ 3,880	$ 113,930

Product Revenue, Net. Product revenue, net was approximately $83.3 million for the three months ended September 30, 2024, compared to $25.1 million for the three months ended September 30, 2023. Product revenue, net for both the three months ended September 30, 2024 and September 30, 2023 consisted of net product sales of BRIUMVI in the United States. In January 2023, we began commercial sales of BRIUMVI within the U.S. following FDA approval.

License, Milestone, Royalty and Other Revenue. License, milestone, royalty and other revenue was $0.6 million for the three months ended September 30, 2024 and $140.7 million for the three months ended September 30, 2023. License, milestone, royalty and other revenue for the three months ended September 30, 2024 is primarily comprised of consideration received for development and regulatory activities performed on behalf of Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm) in accordance with the Commercialization Agreement with Neuraxpharm (see Note 2 for more information). License, milestone, royalty and other revenue for the three months ended September 30, 2023 is predominantly comprised of recognition of the one-time $140.0 million non-refundable upfront payment under the Commercialization Agreement with Neuraxpharm.

Cost of Revenue. Cost of revenue for the three months ended September 30, 2024 was $9.3 million compared to approximately $3.5 million for the three months ended September 30, 2023. Cost of revenue for both the three months ended September 30, 2024 and September 30, 2023 consists primarily of third-party manufacturing, distribution, overhead costs and royalties owed to our licensing partner for BRIUMVI sales. A portion of the costs of producing BRIUMVI sold to date was expensed as research and development prior to the FDA approval of BRIUMVI and therefore it is not reflected in the cost of revenue. We expect the cost of revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories. We expect to use the remaining pre-commercialization inventory for product sales through the first quarter of 2025, after which our product gross margin is anticipated to decrease modestly. The cost of revenue for both the three months ended September 30, 2024 and September 30, 2023 includes $0.3 million and $0.7 million, respectively, of costs related to delivering regulatory support and development services to Neuraxpharm in accordance with the Commercialization Agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $3.0 million for the three months ended September 30, 2024, as compared to $2.9 million during the comparable period ended September 30, 2023.

Other Research and Development Expense. Other research and development expense increased for the three months ended September 30, 2024, by approximately $5.3 million to $17.1 million as compared to the period ended September 30, 2023. The increase in research and development expense during the three months ended September 30, 2024 was primarily due to increased personnel, clinical trial related expenses and manufacturing costs incurred during the period.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $8.7 million for the three months ended September 30, 2024, as compared to $6.3 million during the comparable period ended September 30, 2023. The increase in noncash compensation expense was primarily due to greater recognition of noncash compensation expense for grants to executives during the three months ended September 30, 2024.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled $33.2 million for the three months ended September 30, 2024, as compared to $26.5 million during the comparable period ended September 30, 2023. The increase was primarily due to other selling, general and administrative costs, including personnel, consultants, and third parties associated with the commercialization of BRIUMVI during the three months ended September 30, 2024.

Interest Expense. Interest expense increased by $7.1 million to $10.8 million for the three months ended September 30, 2024, as compared to $3.7 million for the three months ended September 30, 2023. Interest expense for the three months ended September 30, 2024 is comprised of approximately $4.6 million of debt extinguishment costs pertaining to the First Amendment with Hercules, as well as $4.4 million in interest expense pertaining to the Initial Term Loan with Blue Owl during the same period (see Note 7 for more information).

Other Income. Other income totaled $2.7 million for the three months ended September 30, 2024, as compared to $2.9 million during the comparable period ended September 30, 2023.

The following table summarizes the results of operations for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine months ended September 30, 2024	2023
Product revenue, net	$ 206,381	$ 48,868
License, milestone, royalty and other revenue	14,438	140,823
Total Revenue	$ 220,819	$ 189,691
Costs and expenses:		
Cost of revenue	23,087	6,277
Research and development:		
Noncash compensation	8,000	10,162
Other research and development	62,417	48,581
Total research and development	70,417	58,743
General and administrative:		
Noncash compensation	22,593	18,386
Other selling, general and administrative	92,742	73,167
Total general and administrative	115,335	91,553
Total costs and expenses	208,839	156,573
Interest expense	16,967	10,184
Other income	(5,128)	(4,154)
Total other expense, net	11,839	6,030
Net income before taxes	141	27,088
Income tax expense	89	—
Net income	$ 52	$ 27,088

Product Revenue, Net. Product revenue, net was approximately $206.4 million for the nine months ended September 30, 2024, compared to $48.9 million for the nine months ended September 30, 2023. Product revenue, net for both the nine months ended September 30, 2024 and September 30, 2023, consisted of net product sales of BRIUMVI in the United States. In January 2023, we began commercial sales of BRIUMVI within the U.S. following FDA approval.

License, Milestone, Royalty and Other Revenue. License, milestone, royalty and other revenue was $14.4 million for the nine months ended September 30, 2024 compared to approximately $140.8 million for the nine months ended September 30, 2023. License, milestone, royalty and other revenue for the nine months ended September 30, 2024 is comprised of a $12.5 million milestone payment under the Neuraxpharm Commercialization Agreement for the first key market commercial launch of BRIUMVI in the EU, as well as consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement. License, milestone, royalty and other revenue for the nine months ended September 30, 2023 is predominantly comprised of recognition of the one-time $140.0 million non-refundable upfront payment under the Commercialization Agreement with Neuraxpharm (see Note 2 for more information).

Cost of Revenue. Cost of revenue for the nine months ended September 30, 2024 was $23.1 million compared to approximately $6.3 million for the nine months ended September 30, 2023. Cost of revenue for both the nine months ended September 30, 2024 and September 30, 2023 consists primarily of third-party manufacturing, distribution, overhead costs and royalties owed to our licensing partner for BRIUMVI sales. A portion of the costs of producing BRIUMVI sold to date was expensed as research and development prior to the FDA approval of BRIUMVI and therefore it is not reflected in the cost of revenue. We expect the cost of revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories. We expect to use the remaining pre-commercialization inventory for product sales through the first quarter of 2025, after which our product gross margin is anticipated to decrease modestly. The cost of revenue for the nine months ended September 30, 2024 and the nine months ended September 30. 2023 includes $1.4 million and $0.7 million, respectively, of costs related to delivering regulatory support and development services to Neuraxpharm in accordance with the Commercialization Agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $8.0 million for the nine months ended September 30, 2024, as compared to $10.2 million during the comparable period ended September 30, 2023. The decrease in noncash compensation expense was primarily due to decreased vesting of milestone-based grants during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023.

Other Research and Development Expense. Other research and development expense increased for the nine months ended September 30, 2024, by approximately $13.8 million to $62.4 million, as compared to $48.6 million during the comparable period ended September 30, 2023. The increase in other research and development expense during the nine months ended September 30, 2024 was primarily attributable to the Precision License Agreement, as well as manufacturing related expenses during the period, offset by a decrease in clinical trial expenses.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $22.6 million for the nine months ended September 30, 2024, as compared to $18.4 million during the comparable period ended September 30, 2023. The increase in noncash compensation expense was primarily due to greater recognition of noncash compensation expense for grants to executives during the nine months ended September 30, 2024.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled $92.7 million for the nine months ended September 30, 2024, as compared to $73.2 million during the comparable period ended September 30, 2023. The increase was primarily due to other selling, general and administrative costs, including personnel, consultants, and third parties associated with the commercialization of BRIUMVI during the nine months ended September 30, 2024.

Interest Expense. Interest expense increased by $6.8 million to $17.0 million for the nine months ended September 30, 2024, as compared to $10.2 million for the nine months ended September 30, 2023. Interest expense for the nine months ended September 30, 2024 is comprised of approximately $4.6 million of debt extinguishment costs pertaining to the First Amendment with Hercules, as well as increased interest expense pertaining to the Initial Term Loan with Blue Owl during the same period (see Note 7 for details).

Other Income. Other income increased by $1.0 million to $5.1 million for the nine months ended September 30, 2024, as compared to $4.1 million during the nine months ended September 30, 2023. The increase is mainly due to greater accretion income earned from short-term investment securities during the nine months ended September 30, 2024, compared to the comparable period ending September 30, 2023.

LIQUIDITY AND CAPITAL RESOURCES

Historically, we have incurred operating losses; however, during the three and nine months ended September 30, 2024 the Company generated net income. Additionally, during the twelve months ended December 31, 2023, the Company experienced a net profit due to a $140.0 million non-refundable upfront payment recognized as license revenue in the third quarter of 2023 as part of our ex-U.S. commercialization agreement (the Commercialization Agreement) with Neuraxpharm (see Note 2 for more information). We may incur operating losses in the near term and may never become profitable. As of September 30, 2024, we have an accumulated deficit of $1.6 billion.

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, from our loan and security agreements, the upfront payment from the Commercialization Agreement (see Note 2 for more information), and from product revenue from drug sales of BRIUMVI. During the nine months ended September 30, 2024, we generated $206.4 million in product revenue from drug sales of BRIUMVI. BRIUMVI is currently our only marketed product. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. We expect to continue to incur significant research and development expenses, as well as significant commercialization and outsourced manufacturing expenses as we continue to commercialize BRIUMVI. 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 a net profit. We may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

As of September 30, 2024, we had $341.0 million in cash, cash equivalents, and investment securities. The Company believes its existing cash, cash equivalents, and investment securities, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will be sufficient to fund our anticipated operating cash requirements for at least twelve months following the date of this filing.

The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, our commercialization efforts for BRIUMVI, preparations for the potential commercialization of our other drug candidates, and the timing, design and conduct of clinical trials for our drug candidates as well as the costs associated with licensing or otherwise acquiring new product candidates. We may be dependent upon significant future financing to provide the cash necessary to execute our ongoing and future operations, including the commercialization of any of our drug candidates.

Discussion of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023:

	Nine months ended September 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (14,876)	$ (18,203)
Net cash used in investing activities	$ (16,824)	$ (5,896)
Net cash provided by (used in) financing activities	$ 134,599	$ 72,706

Cash used in operating activities for the nine months ended September 30, 2024 was $14.9 million as compared to cash used in operating activities of $18.2 million for the nine months ended September 30, 2023. The decrease in net cash used in operating activities was due to greater revenue during the nine months ended September 30, 2024, offset by higher operating expenditures and an increase in cash used for inventory purchases during the same period.

Net cash used in investing activities for the nine months ended September 30, 2024 was $16.8 million as compared to $5.9 million used in investing activities for the nine months ended September 30, 2023. The increase in net cash used in investing activities was primarily due to increased investment in short-term securities during the nine months ended September 30, 2024.

Net cash provided by financing activities for the nine months ended September 30, 2024 was approximately $134.6 million as compared to net cash provided by financing activities of $72.7 million for the nine months ended September 30, 2023. The increase in net cash provided by financing activities during the nine months ended September 30, 2024 is mainly due to the proceeds from the new loan with Blue Owl, offset by the payoff of our prior loan with Hercules.

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, 2023, and refer to Note 1 in this Quarterly Report on Form 10-Q for significant accounting policies due to commercialization for revenue recognition, gross-to-net sales adjustments, accounts receivable, inventory, and cost of revenue. Of these policies, the following are considered critical to an understanding of our Unaudited Condensed Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments: stock-based compensation expenses, and fair value measurement of financial liabilities. Refer to "Note 2 – Revenue", "Note 5 – Fair Value Measurements" and "Note 6 – Stockholders' Equity" respectively, 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, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2024, management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) 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, 2024, our disclosure controls and procedures were not effective due to the material weakness in internal control over financial reporting described below.

In light of the material weakness described below, management performed additional analyses and other procedures to ensure that our consolidated financial statements were prepared in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP). Accordingly, management believes that the consolidated financial statements included in this Quarterly Report fairly present, in all material respects, our financial position, results of operations, and cash flows as of and for the periods presented, in accordance with U.S. GAAP.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The Company identified that a process-level control over share-based payment awards was not designed effectively. This ineffectively designed control was attributable to insufficient risk assessment with regards to non-routine share-based payment awards. This control deficiency resulted in immaterial misstatements in related accounts. Furthermore, the control deficiency described above created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis. Therefore, we concluded that the deficiency represents a material weakness in the Company’s internal control over financial reporting and our internal control over financial reporting was not effective.

Management’s Plan to Remediate the Identified Material Weakness

The Company will implement enhanced risk assessment procedures to ensure that all non-routine share-based payment awards are appropriately identified and evaluated. Further, the Company will design additional preventative controls around non-routine share-based payment awards to ensure the appropriate recognition and measurement of such awards. Management will report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status, and resolution of internal control deficiencies.

We anticipate that the material weakness will be fully remediated before December 31, 2024, but the material weakness cannot be considered fully remediated until the updated policies and training have been in place and operated for a sufficient period of time to enable management and KPMG LLP to test and to conclude on the operating effectiveness of the controls.

Changes in Internal Control Over Financial Reporting

Other than the steps to remediate the material weakness discussed above, 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 period ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS.

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

Risks Related to Commercialization

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

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

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

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

In addition, global health concerns 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 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., including but not limited to, the EMA in the EU and the MHRA in the UK. These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market BRIUMVI, or negatively impact its overall clinical profile. As of September 18, 2024, we announced updated and long-term data from the Open-Label Extension of our ULTIMATE I & II Phase 3 studies demonstrating a consistent safety profile, 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 foreign regulatory authority approves, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices (cGMPs), with Good Clinical Practices (GCPs), for any clinical trials that we conduct post-approval, and with Good Laboratory Practices (GLPs) for any nonclinical studies. Later discovery of previously unknown problems with a product or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes or product recalls, suspension or revocation of product approvals, product seizure or detention, refusal to permit the import or export of products, and injunctions or the imposition of civil or criminal penalties, all of which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

As BRIUMVI or any future approved products are used more widely or for a longer duration after being brought to market, data may emerge from clinical studies, including confirmatory or other post-marketing studies, or from adverse event reporting 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 caused by BRIUMVI or other products or product candidates within the RMS space following introduction into the market, a number of potentially significant negative consequences could result, including:

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

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

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

The precise incidence and/or prevalence of RMS are unknown. Our projections for BRIUMVI in RMS are based on estimates and our current knowledge and understanding of the disease. These estimates are typically based on one-on-one and group interactions with target physicians and other sources available at the time we make the estimates, including the scientific literature, healthcare utilization databases and market research. Although we believe our estimates are reasonable, many factors may limit their accuracy. For example, the sources we use to make the estimates may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases and the number of patients 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 diseases that we are, including within the neurological and immunological fields, some in direct competition with us. We may also compete with these organizations to recruit commercial and other key personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

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

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

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

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

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

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

In addition, we have entered into a commercialization agreement, and may enter into additional agreements in the future, that facilitate commercialization of BRIUMVI and/or future products that receive approval in markets outside the U.S. through partnerships. On February 26, 2024, our partner commercially launched BRIUMVI in Germany, the first European market in which BRIUMVI has launched. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any products or product candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product or product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

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

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

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

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

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive 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 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 incurred significant operating losses since our inception, and we may incur losses in the future.

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

Since inception, we have focused our efforts and financial resources on clinical trials, manufacturing of our 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. Since inception, we have incurred significant operating losses. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. BRIUMVI is currently our only marketed product. 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. 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 a net profit. We may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue. 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 become and 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 projections or guidance with respect to BRIUMVI or our product candidates, if approved. To obtain significant and sustained revenues and meet our revenue projections or guidance, we must succeed, either alone or with others, in (i) obtaining and maintaining regulatory approval for our products and product candidates; and (ii) 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 foreign marketing approval for our product and product candidates;
- obtain approval from the FDA and foreign equivalents to market and sell our product and product candidates, and maintain FDA, MHRA and EMA approvals of BRIUMVI for RMS;
- establish and maintain commercial manufacturing capabilities with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our product and product candidates;
- expand on our commercialization infrastructure to commercialize BRIUMVI, and/or entering into collaborations with third parties;
- 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.

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

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

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

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

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

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

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or other arrangements. We do not have any committed external source of funds, other than funds already borrowed under the Financing Agreement that we entered into with Blue Owl Capital Corporation, HealthCare Royalty and Blue Owl Capital in August 2024 (*see* Note 7 to our condensed consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or products and product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, which could limit our ability to expand our business operations and could harm our overall business prospects.

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

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

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

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

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

In February 2019, we entered into a Loan and Security Agreement with Hercules Capital, Inc., a Maryland corporation (Hercules), and on December 30, 2021, the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules, which was amended on March 31, 2023. On August 2, 2024, we repaid all outstanding principal and accrued interest and fees under the Amended Loan Agreement, as amended, and the Amended Loan Agreement was effectively terminated.

On August 2, 2024, 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 and Blue Owl Capital under the Financing Agreement (as defined below).

The Initial Term Loan is governed by a financing agreement, dated August 2, 2024 (the Financing Agreement), which provides for (i) a single draw of the Initial Term Loan on the Closing Date and (ii) an uncommitted additional facility in an aggregate principal amount of $100 million (*see* Note 7 to our condensed consolidated financial statements for more information).

All obligations under the Financing Agreement are secured by a lien on substantially all of assets of the Company and 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 its outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

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 their 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 the Company. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things (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.

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

Risks Related to Drug Development and Regulatory Approval

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

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

- successful completion of our clinical programs with positive results that support a finding of effectiveness and an acceptable safety profile of our product candidates in the intended populations within the timeframes we have projected;
- Investigational New Drug Applications (INDs) and clinical trial applications (CTAs), 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 have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate, through adequate and well-controlled clinical trials, that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising 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 initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

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

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

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete 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.

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

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

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- the FDA or other regulatory authorities or institutional review boards (IRBs) or ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or in a country; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional 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 or ECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises international conflicts such as the Russian invasion of Ukraine or the Israel-Hamas war, economic instability, or natural disasters;
- regulatory authorities may revise the requirements applicable to our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs or ECs to suspend or terminate the trials, or reports may arise from 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 Data and Safety Monitoring Board (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 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 approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements or post-marketing commitments;
- be subject to increased pricing pressure; or
- have the drug removed from the market after obtaining marketing approval.

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

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

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

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

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

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, and pharmacovigilance and adverse event reporting of our product or product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities worldwide. In the United States, we are not permitted to market a 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 foreign regulatory authorities in the timelines we project or at all, we may be unable to generate the revenues that we may project or generate revenues at levels sufficient to sustain our business.

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

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

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

Even if we succeed in obtaining regulatory approval for a product candidate, the FDA may require, 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.

We are currently focusing the majority of our efforts on developing BRIUMVI (ublituximab-xiiy) and azercabtagene zapreleucel (azer-cel) for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

We are currently focusing the majority of our resources and efforts on developing BRIUMVI (ublituximab-xiiy) and azercabtagene zapreleucel (azer-cel). As a result, we may forego or delay the pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target markets for BRIUMVI (ublituximab-xiiy) and azercabtagene zapreleucel (azer-cel), 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 candidate(s) or program(s).

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

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

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

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their respective jurisdictions.

We have been and may continue to conduct clinical trials globally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authorities 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 United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority 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 foreign jurisdictions.

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

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

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

To the extent possible and commercially practicable, we plan to develop back-up strategies for raw materials and manufacturing and testing services for our commercial products. Given the long lead times and cost of establishing additional commercial manufacturing sites we expect that we will rely on single contract manufacturers to produce our commercial products under current Good Manufacturing Practice, or cGMP, regulations for the foreseeable future. Our commercial manufacturing partners have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. 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 manufacturers either before or after commercialization, the FDA and corresponding foreign regulatory agencies may need to approve these new manufacturers in advance, which will involve testing, regulatory submissions, and additional inspections to ensure compliance with FDA and other regulations and standards, and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Some of our product and product candidates are currently manufactured in relatively small batches for use in 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.

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

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

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

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

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

There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, limit price increases, evaluate the relationship between pricing and manufacturer patient programs, and reform government health care program reimbursement methodologies for prescription drugs. For example, the Bipartisan Budget Act of 2018 (BBA) increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70% effective as of January 1, 2019, ultimately increasing the liability for brand drug manufacturers. In addition, on September 20, 2024, the Centers for Medicare & Medicaid Services 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. We expect that health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased manufactured financial liability and additional downward pressure on the price that we may receive for any of our product candidates, if approved. Any reduction in reimbursement from Medicare or other government health care programs may result in a similar reduction in payments from private payors.

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

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

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

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

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

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

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

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

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

Inadequate funding for 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. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the 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.

Disruptions at the FDA and other agencies may also extend the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, 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 critical employees and stop 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, upon completion of this offering and in our operations as a public company, 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 FDA, EMA and MHRA approval of BRIUMVI, we are subject to additional extensive healthcare statutory and regulatory requirements and oversight by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our past, current and future relationships, arrangements and interactions with these professionals and entities, as well as with patients and patient advocacy organizations expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product and product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 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. The Centers for Medicare & Medicaid Services (CMS) has the potential to impose penalties for violations of the Physician Payment 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 the 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;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
- the FDCA and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the Drug Supply Chain Security Act (DSCSA), which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the U.S.; and
- state law equivalents of some of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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

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

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

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

Within the United States, HIPAA 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 is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act (CCPA), went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. Colorado, Connecticut, Washington, Utah, Virginia and Iowa have also enacted data privacy statutes. Among other things, these state-specific laws create new 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. 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 Washington My Health My Data Act also contains a private right of actions. 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. In addition to the laws discussed above, we may see more stringent federal and state privacy legislation passed in 2024 and beyond, as increased cyber-attacks have once again put a spotlight on data privacy and security in the U.S. and other jurisdictions. We cannot predict where new legislation might arise, the scope of such legislation, or the potential impact to our business and operations. We expect to incur additional costs to ensure that our data privacy and security policies, procedures, and activities comply with applicable and evolving legal requirements.

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

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

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

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

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

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

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

Any 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.

The U.S. political and economic environment could materially impact our business operations and financial performance, and uncertainty surrounding the potential legal, regulatory and policy changes by a new U.S. presidential administration may directly affect us and the global economy.

The political and economic environment in the United States and elsewhere has resulted in and will continue to result in some uncertainty. Changing regulatory policies because of the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition and operating results. Failure to adapt to or comply with evolving regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital and our stock price.

Further, a change in the U.S. presidential administration and congressional seat turnover following the 2024 election cycle may result in increased regulatory and economic uncertainty. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and personnel changes, which could lead to changes involving the level of oversight and focus on the pharmaceutical industry; however, the nature, timing and economic and political effects of such potential changes remain highly uncertain. Any future changes in federal and state laws and regulations, as well as the interpretation and implementation of such laws and regulations, could affect us in substantial and unpredictable ways. At this time, it is unclear what laws, regulations and policies may change and whether future changes or uncertainty surrounding future changes will adversely affect our operating environment and therefore our business, financial condition and results of operations.

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, 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 European Economic Area and comparable foreign regulatory authorities for any drug candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, clinical investigators, CROs, institutional review boards, and non-clinical laboratories. If we, our CROs, our investigators or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our CROs or 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, e.g., ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On July 28, 2023, we entered into a commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), pursuant to which Neuraxpharm has the right to commercialize BRIUMVI in certain markets outside of the U.S. On February 26, 2024, Neuraxpharm announced the commercial launch of BRIUMVI in Germany and expects to launch BRIUMVI in additional international markets as well. 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 (e.g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the agreement with us);
- failure by a collaboration or commercialization partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;
- failure by a collaboration or commercialization partner to timely deliver accurate and complete medical or clinical information to us or to maintain adequate and effective internal control over its pharmacovigilance activities and reporting may negatively affect our ability to meet our reporting obligations as required by the FDA and other regulatory bodies;
- collaboration or commercialization partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or product candidates;
- decisions by a collaboration or commercialization partner to prioritize others of its current or future products more highly than our drug products or our product candidates when it performs its duties;
- possible disagreements with a collaboration or commercialization partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and
- the 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 the Company in the event of a breach by Neuraxpharm, there can be no assurance that the Company and Neuraxpharm will agree on a cure for such a breach, and in the event of termination, there can be no assurance that the Company would be appropriately compensated and/or recover any losses sustained. Due to these factors and other possible disagreements with our collaboration and commercialization partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

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

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

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

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

We may not be able to negotiate additional collaborations on a timely basis, on 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.

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

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

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

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

These risks and uncertainties include the following:

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The patent laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States patent law does. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a 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 parties review, post-grant review or interference proceedings. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by patents and patent applications for our drug candidates is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates.

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

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

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

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections 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 permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond 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 parties review against the asserted patents, which may lead to a finding that all or some of the claims of the asserted patents are invalid. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our pending patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of November 5, 2024, we had 319 employees. To manage our anticipated future growth and focus in neurology and immunology, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these activities. Due to our limited resources, we may not be able to effectively manage the expansion and shift of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our transition to a strategy primarily focused on neurology and immunology, our expenses may increase more than expected our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and changes to our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As another example, in August 2022, the Inflation Reduction Act of 2022 (the IRA) was enacted, and, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning after December 31, 2022. To the extent that such 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. On December 14, 2023, President Biden announced that, under the IRA, dozens of pharmaceutical companies are required to pay rebates to Medicare for price hikes on prescription drugs.

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

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

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

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

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

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 climate change has the potential to negatively affect our business, results of operations, financial condition and growth prospects. The adverse impacts of climate change include (i) physical risks such as increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat, (ii) risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and (iii) social and human effects (such as population dislocations and harm to health and well-being).

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 we 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 change 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 may directly or indirectly incur. If the manufacturing facilities of our third-party manufacturers are unable to operate for any reason, even for a short period of time, any or all of our research and development programs or commercialization efforts may be harmed. Any material interruption could have a material and adverse effect on our business.

New legal or regulatory requirements may also be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in our manufacturing partners being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrading of facilities to meet new building codes, and the redesign of utility systems, which could increase our third-party manufacturers' operating costs, including the cost of electricity and energy used to develop our products. Our supply chain as a whole would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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

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

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

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

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

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

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

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

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

We have identified a material weakness in our internal control over financial reporting related to non-routine share-based payment awards, and if our remediation of such material weakness is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

During the preparation of our unaudited condensed consolidated financial statements for the period ended June 30, 2024, we identified a material weakness in our internal control over financial reporting related to controls around non-routine share-based payment awards. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness identified pertains to certain process-level controls over share-based payment awards for stock awards with market conditions. To remediate the material weakness in the Company's internal control over financial reporting, the Company will implement enhanced risk assessment procedures to ensure that all non-routine share-based grants are appropriately identified and evaluated. Further, the Company will design additional preventative controls around non-routine share-based payment awards to ensure the appropriate recognition and measurement of such awards at the grant date.

The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time to enable management and our independent registered public accounting firm to test and to conclude that these controls are operating effectively. Until this material weakness is remediated, we plan to continue to perform additional analyses and other procedures to ensure that our consolidated financial statements are prepared in accordance with GAAP.

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. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

Furthermore, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. 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. 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. Any failure to implement and maintain effective internal control over financial reporting could adversely affect the results of periodic management evaluations.

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

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

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

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

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 August 2024, we announced that our Board of Directors had authorized a share repurchase program of up to $100 million of our outstanding shares of common stock. 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.

There can be no assurance of any future share repurchases or share repurchase program authorizations. 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***
July 2024 (July 1st to July 31st, 2024)	-	-	-	-
August 2024 (August 1st to August 31st, 2024)	9,000	$23.58	9,000	$99,787,788
September 2024 (September 1st to September 30th, 2024)	83,301	$23.25	83,301	$97,851,216
Total	92,301	$23.28	92,301	$97,851,216

*Transaction fees are excluded.

On August 2, 2024, the Company announced that its Board of Directors had authorized and approved a share repurchase program for up to $100 million of the currently outstanding shares of the Company's common stock. Repurchases under the 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 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 OF 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, 2024, 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.

10.1#	Master Services Agreement between FUJIFILM DIOSYNTH BIOTECHNOLOGIES NORTH CAROLINA, INC, FUJIFILM DIOSYNTH BIOTECHNOLOGIES DENMARK APS and TG Therapeutics, Inc., effective October 8, 2024.
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 7, 2024.
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 7, 2024.
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 7, 2024.
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 7, 2024.
101*	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
** Furnished herewith.
# Certain confidential portions of this exhibit have been omitted pursuant to Item 601(b) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TG THERAPEUTICS, INC.

Date: November 7, 2024

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

Exhibit 10.1

(1) FUJIFILM DIOSYNTH BIOTECHNOLOGIES NORTH CAROLINA, INC.;

(2) FUJIFILM DIOSYNTH BIOTECHNOLOGIES DENMARK APS

AND

(3) TG THERAPEUTICS, INC.

Partners for *Life*
Advancing tomorrow's medicines

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THIS AGREEMENT is made on the date it is signed by the last signing party.

BETWEEN

(1) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES NORTH CAROLINA, INC.** at 100 Biotechnology Avenue, Holly Springs, NC 27540 United States of America ("**FDBN**")

(2) **FUJIFILM DIOSYNTH BIOTECHNOLOGIES DENMARK APS** incorporated and registered in Denmark with company number 26060702 whose registered office is at Biotek Alle 1, 3400 Hillerød, Denmark ("**FDBD**")**;** and

(3) **TG THERAPUTICS, INC.** a Delaware Corporation whose registered office is at 3020 Carrington Mill Bvld, Suite 475, Morrisville, NC 27560 (the "**Customer**").

BACKGROUND

(A) Fujifilm (as defined below) is a biopharmaceutical contract development and manufacturing organization. Customer wishes to appoint Fujifilm to carry out development and manufacturing services in relation to certain of the Customer's products.

(B) Fujifilm and the Customer have agreed to work together on the terms and conditions contained in this Agreement.

AGREED TERMS

1. **DEFINITIONS AND INTERPRETATION**

1.1 In this Agreement the following words have the following meanings unless inconsistent with the context:

"Actual Production Expenditure" has the meaning given to it in Schedule 1;

"Affiliate" means in relation to an entity, each or any other entity who for the time being, directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such entity. For the purposes hereof (and clause 14.2), "control" shall mean: (a) holding the majority of the voting rights or share capital of such entity; (b) any power (whether direct or indirect and whether by the ownership of share capital, the possession of voting power, contract, or otherwise) to appoint and/or remove all or such of the members of the board or other governing body of a body corporate as are able to cast the majority of the votes capable of being cast by members of that board or body on all, or substantially all, matters, or (c) otherwise to control or have the power to control the policies, management and affairs of that body corporate;

"Ancillary Charges"	has the meaning given to it in clause 8.2.3;
"Ancillary Services"	has the meaning given to it in Schedule 1 (Charges): see Part 1 for the position pre Commercial Trigger and Part 2 for the position post Commercial Trigger;
"Annual Service Fee"	the fee described in Schedule 1;
"Applicable Laws"	applicable law, regulations and binding guidance which applies in the jurisdiction in which a Program is being performed;
"Authorized Third Party"	has the meaning given to it in clause 12.1;
"Background IP"	all Intellectual Property Rights controlled, owned or jointly owned by any party (or a third party on its behalf) prior to the Effective Date or developed independently from a Program. Fujifilm's proprietary manufacturing, expression or purification technologies, including: (a) an expression system within the scope of international patent application [***] (the "pAVEway™ Expression System"); (b) expression technology within the scope of international patent application [***] (the "Apollo™ Expression Technology"); and (c) Fujifilm's proprietary alcohol oxidase yeast Pichia pastoris expression system (the "Yeast Expression System"); ("**Fujifilm Expression Technology**") is Fujifilm's Background IP;
"Batch"	a quantity of Product that is produced from a run of the Process;
"Batch Cancellation Fee"	the Batch Cancellation Fee described in Schedule 1;
"Batch Fee"	(a) in relation to Batches produced pursuant to the R&D Services, if the Batch Fee is clearly described in the applicable SoW the Batch Fee for that SoW shall be the Batch Fee described in the SoW; however, if the Batch Fee is not clearly described in the applicable SoW it will be deemed to be, in respect of any Batch under that SoW, all Charges for Fujifilm Services in respect of the manufacturing stages carried out in connection with that Batch; (b) in relation to Batches produced pursuant to the Commercial Manufacturing Services, the price per Batch agreed in the applicable PSA;

"Business Day"	(a) in relation to notices given under this Agreement (rather than a specific Scope of Work or PSA) a day other than a Saturday, Sunday, or public holiday in the US or Denmark and/or the country in which the Customer's head office is located; and (b) in relation to notices given under a specific Scope of Work or PSA, a day other than a Saturday, Sunday, or public holiday in the US if FDBN is a contracting party, Denmark if FDBD is a contracting party and/or the country in which the Customer's head office is located;
"cGMP"	Represents principles and practices applied to the manufacture of pharmaceutical materials as supported by the following cGMPs for drugs, as applicable to the material being manufactured (e.g. non-sterile bulk API / Drug Substance(s)): (i) the U.S. Federal Register volume 66 No 186 the FDA Regulations 21 CFR Part 11, 210, 211, 600 and 610 and ICH Q7; (ii) the Rules governing medicinal products in the European Union under the EC, EudraLex, Volume 4 – Guidelines for Good Manufacturing Practices for medicinal products for human and veterinary use. Part I – Basic Requirements for Medicinal Products. Part II – Basic Requirements for Active Substances used as Starting Materials, Part III GMP related documents, Annexes and Part IV GMP requirements for Advanced Therapy Medicinal Products, as applicable to the Product manufactured; and (iii) United Kingdom Human Medicines Regulations 2012 (HMR, SI 2012/1916, as amended), Guidelines on Good Manufacturing Practice, Parts and Annexes as EudraLex, Volume 4 above;
"cGMP Batch"	a Batch identified in a Scope of Work or PSA (as applicable) which is intended to be manufactured during a manufacturing stage and subject to Disposition in each case in accordance with cGMP;
"Change"	has the meaning given to it in clause 13;
"Charges"	has the meaning set out in clause 8.2;
"Commercially Reasonable Efforts"	shall mean with respect to an activity to be carried out by a party, the carrying out of such activity in a diligent manner, which, in the case of Fujifilm, requires using the efforts of sufficient numbers of personnel appropriately qualified by experience and training, as would be reasonably applied by a qualified manufacturer of biologics for Drug Substances of similar nature, complexity, and developmental stage in the same or similar circumstances, or, in the case of Customer, using such efforts as would be typically be used in the biopharmaceutical industry by companies of comparable resources and expertise. "Commercially Reasonable Efforts" requires reasonably prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity, but does not require the taking of actions which would require either party to violate Applicable Laws or break any existing contractual commitments with third parties.;

“Commercial Manufacturing Services”	the production, testing and Disposition of cGMP Batches at scale under a PSA with the intention that the Conforming Batches produced under those services will be supplied by Fujifilm, and used by the Customer, as commercial Product;
“Commercial Trigger”	Is the date of approval of the BLA amendment in the US territory allowing the commercial use of the PPQ batches.
“Competitor”	a contract development and/or manufacturing organization in the biopharmaceutical industry;
“Confidential Information”	the fact and terms of this Agreement, any Scope of Work and any PSA, and all information (in whatever form) in respect of the business of each of the parties and each of its Affiliates including any ideas; business methods; finance; prices, business, financial, marketing or development plans; products or services, know-how or other matters connected with products or services manufactured and/or marketed; customer lists or details; computer systems and software; which is (in each case) provided to, or obtained by, one party from the other;
“Conforming Batch”	a cGMP Batch which has been produced in accordance with cGMP and which meets the Product Specification and all requirements currently filed for approval in the US and EU market territories for the Product at the time of manufacture which Customer has provided to (and agreed to by) Fujifilm;
“Consumable”	a consumable item used or intended for use in a Program, including PEG, reagents (including analytical reagents), plasmids, raw materials, packaging components, chromatography resins, filters, filtration membranes, media, buffer bags, refold bags, change-over parts (including tubing, hoses, seals and gasket sets) disposable analytical test kits, in-process measurement probes, columns (including analytical columns) and disposable containers;

"Consumables Advance Payment"	has the meaning given to it in Schedule 1;
"Customer Deliverables"	the deliverables to be supplied by the Customer described in a SoW or PSA (as applicable);
"Customer Foreground IP"	all Foreground IP that constitutes an improvement or modification which is specific to the Customer's Background IP which has been provided to Fujifilm by the Customer pursuant to a Program;
"Delay"	has the meaning given to it in clause 14.1.1;
"Demonstration Batch"	a Batch which is manufactured in a non cGMP R&D facility for demonstration purposes and which is not intended for human use;
"Deviation"	a cGMP deviation as detailed in the Quality Agreement;
"Disposition"	the Stage during which (i) the Product is tested for compliance versus the Product Specification; (ii) all production instruction and analytical records relating to cGMP manufacture of each cGMP Batch prepared by Fujifilm are reviewed; and (iii) a Fujifilm recommendation for Product release or reject is made; in each case as applicable;
"Drug Product"	the final dosage form of product which is, or contains, Product in association with other active or inactive ingredients;
"Drug Substance"	any substance or mixture of substances intended to be used in the manufacture of a Drug Product and that, when used in the production of a drug, becomes an active ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect on the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body;
"Effective Date"	the date of final signature by all parties to this Agreement being the date last signing party signs this Agreement;
"Engineering Batch"	a Batch that is manufactured in a cGMP Facility at scale using the Process but which is not intended for human use;
"Facility"	any of Fujifilm's manufacturing facilities in which a Program will be performed;
"Force Majeure Event"	any event or circumstances outside the reasonable control of a party affecting its ability to perform any of its obligations under this Agreement including act of God, fire, flood, severe weather, epidemic or pandemic, war, revolution, acts of terrorism, riot or civil commotion, acts of government, trade embargo, labor disputes (excluding labor disputes involving the party in question), unforeseeable interruption of utility service restraints or delays affecting shipping or carriers, inability or delay in obtaining supplies of adequate or suitable materials, inability or delay in obtaining third party services, unforeseeable breakdown or failure in equipment or machinery. cyber-attack, currency restrictions but shall not include the failure of Drug Product in clinical trials or failure of Drug Product to gain regulatory approval;

"Foreground IP"	all Intellectual Property Rights that arise or are obtained or developed by or on behalf of any party in the course of the performance of a Program;
"Fujifilm"	FDBN and/or FDBD as the context requires in accordance with the clause;
"Fujifilm Foreground IP"	all Foreground IP other than Customer Foreground IP;
"Fujifilm Services"	either the R&D Services or the Commercial Manufacturing Services, as described in the relevant Scope of Work or PSA (as applicable), but in each case excluding the Ancillary Services;
"Gross Negligence"	a conscious and voluntary disregard of the need to use reasonable care, which is likely to cause foreseeable grave injury or harm to persons, property, or both;
"Historic Documents"	any historic contractual documentation which cover the same subject matter as a Program as identified in the relevant SoW or PSA (as applicable);
"Indemnify"	on demand to indemnify and keep indemnified, and hold harmless, the party to be indemnified on an after tax basis;
"Initial Term"	has the meaning given to it in the relevant PSA;
"Intellectual Property Right"	any current and future intellectual property rights and interests including patents, utility models, designs, design rights, copyright (including rights in software), decryption rights, database rights, trade marks, rights pursuant to passing off, service marks, business and trade names, domain names, know-how, results, data, databases, formulations, compounds, rights in biological or chemical materials, rights under data exclusivity laws, rights under unfair competition laws, topography rights, inventions, rights in confidential information (including technical and commercial trade secrets); supplementary protection certificates and image rights, and rights of a similar or corresponding character in any part of the world, in each case whether registered or not and including any application for registration and renewals or extensions of such rights in any country in the world and whether subsisting now or in the future;

"Latent Defect"	A defect in a Batch that was present at the time of Disposition but was discovered after Disposition (but within the time frame set forth in clause 6 governing Latent Defects) that renders the Batch a Non-Conforming Batch.
"Liabilities"	any (i) liabilities of any nature, whether accrued, absolute, contingent or otherwise and whether in contract, tort (including negligence) or otherwise; (ii) losses, costs (including internal costs/overheads), damages, fines or expenses including reasonable legal fees; and (iii) claim, demand, proceeding, action or cause of action including those by third parties; in each case howsoever arising. "**Liability**" shall be construed accordingly;
"Material Review Board" or "MRB"	a cross-functional committee, led by quality assurance, that consists of representation from program management, quality control (as applicable), and manufacturing. Customer representation is required;
"Maximum Annual Quantity"	has the meaning given to it in the relevant PSA;
"Minimum Annual Quantity"	has the meaning given to it in the relevant PSA;
"Modifications"	a modification to a Facility; or equipment (including Process specific qualification and installation of existing equipment), required in order to perform a Process and detailed in the applicable Scope of Work or PSA (as applicable)*;*
"Non-Conforming Batch"	a cGMP Batch which has not been produced in accordance with cGMP and/or does not meet the Product Specification;
"Non-Manufacturing Stage"	any Stage of a Program, which is not a manufacturing stage, including (for clarity) the production and testing of Demonstration Batches;
"Order"	has the meaning given to it in Schedule 2;
"Process"	a particular process used, or to be used, for manufacture of a Product;
PPQ Batch	shall mean a Conforming Batch which is expected to be distributed commercially and which is produced from a process validation run conducted by Fujifilm to (i) demonstrate and document the consistency and reproducibility of the manufacturing Process at the Facility, and (ii) support the regulatory approval of both the Product manufactured and the manufacturing Process at the Facility each as defined in the Program Plan

"Process Specification"	the Process operating parameters and specifications as documented in (i) pre Commercial Trigger: the QA Documents (including Deviations) which has been agreed by the parties for cGMP Batch production and (ii) following the Commercial Trigger: the Biologics License Application (BLA);
"Process-Specific Consumable"	a Consumable which is required to operate the Process and which is specific to the Process or a Consumable which is required in such large volumes as would not be possible for Fujifilm to consume during other manufactures and/or within the shelf life of such Consumable;
"Process-Specific Equipment"	an item of equipment which is required by Fujifilm to operate the Process and which is specific to the Process in addition to that equipment which Fujifilm uses in its Facilities as at the SoW Effective Date or PSA Effective Date (as applicable) (which existing equipment is not already dedicated to other customer(s) of Fujifilm);
"Product"	the particular product or substance (compound, reagent, intermediate or molecule) created during and as a result of performing the Process. The name of the relevant Product is identified in the applicable Scope of Work or PSA (as applicable);
"Product Specification"	the Product specification for Product which is documented in a QA Document.
"Production Year"	a period of time used in conjunction with Commercial Manufacturing Services, being a period of [***] ([***]) consecutive calendar [***] ending on [***] [***], except that the first Production Year of this Agreement shall commence on the applicable Commercial Manufacturing Services PSA Effective Date and end on the next following [***] [***], and the last Production Year of this Agreement shall commence on [***] [***] of the year in which this Agreement terminates or expires and end on the date of termination or expiry of this Agreement;
"Program"	a program of work for development and commercial manufacture of the Product, as set out in the applicable Scope of Work (or more than one Scope of Work, as the case may be) and/or PSA and to be carried out by Fujifilm in accordance with the terms of this Agreement;
"Program Cancellation Fee"	an amount equal to the sum of: (i) the relevant Batch Cancellation Fee in respect of any cancelled manufacturing stages during the R&D Services; (ii) the amount calculated under clause 14.3.1 in respect of cancelled Non-manufacturing stages during the R&D Services; and (iii) the sum payable under clause 14.4.1 where Commercial Manufacturing Services are terminated under clause 14.2;

"Program Manager"	the Program manager appointed by each of Fujifilm and the Customer under the applicable SoW or PSA, as applicable;
"Program Plan"	the Program plan controlled by Fujifilm's Program Manager and communicated to the Customer from time to time;
"PSA"	a product specific addendum setting out the Commercial Manufacturing Services to be undertaken by Fujifilm for the Customer;
"PSA Effective Date"	for each PSA, the date that the PSA is fully signed by all relevant parties;
"QA Documents"	the Quality Agreement and the Process Control Strategy and In Process Control ("IPC") documents produced and approved in accordance with the Quality Agreement or any cGMP documents agreed by the parties in writing;
"Quality Agreement"	the document agreed by the parties which sets out the mutually agreed quality standards applicable for any cGMP activity under a Program;
"R&D Services"	technical consultancy services to be provided by Fujifilm under a Scope of Work that are developmental in nature including technology transfer of a process to Fujifilm and any manufacturing that happens before the commencement of Commercial Manufacturing Services;
"Regulatory Authority"	the U.S. Food and Drug Administration, the European Medicines Agency, the Medicines & Healthcare products Regulatory Agency, the Danish Medicines Agency, and any successor to any such entities;
"Scope of Work" or "SoW"	the document setting out the detail of the R&D Services to be undertaken by Fujifilm for the Customer;
"Shelf Life"	has the meaning given to it in the relevant PSA;
"SoW Effective Date"	for each Scope of Work, the date that the Scope of Work is fully signed by all relevant parties;
"Special Waste"	waste or effluent which requires special handling including waste or effluent which is required to be collected in a special container (for example by tanker) for external disposal or which requires incineration;
"Stage"	a stage of a Program as described in a SoW or the manufacture of one cGMP Batch under a PSA, as applicable. For the purposes of clause 9, a sub-stage described in a SoW (for example a Stage that is described by the Stage number and a suffix such as Stage 1A) shall be deemed to be an independent Stage in its own right;

"Subcontracted Work"	work subcontracted by Fujifilm under clause 21.3 but excluding any work subcontracted by Fujifilm to its Affiliates;
"Subsequent Term"	has the meaning given to it in the relevant PSA;
"Tax"	any and all taxes, charges, levies, assessments and other fees of any kind imposed by any governmental or other authority (including, but not limited to, value added tax, sales tax or any other similar type of turnover tax); and
"Willful Misconduct"	a knowing violation of a reasonable and uniformly enforced rule or policy. It means intentionally doing that which should not be done or intentionally failing to do that which should be done, knowing that injury or harm will probably result or recklessly disregarding the possibility that injury or harm may result.

1.2 In this Agreement (except where the context otherwise requires) any words following the terms " **including**", "**include**", "**for example**" or any similar expression are by way of illustration and emphasis only and shall not limit the generality or extent of any other words or expressions.

1.3 Each Scope of Work and each PSA will be entered into by FDBN or FDBD or a combination of FDBN and/or FDBD and, subject to clause 18.3 each reference to Fujifilm or a "party" in this Agreement shall apply only to such of FDBN and/or FDBD as is carrying out the Program under the relevant Scope of Work or PSA. Whichever of FDBN or FDBD has entered into the Scope of Work or PSA in respect of that Program shall be fully and solely responsible for the obligations and liabilities of that party under the Scope of Work or PSA (as applicable).

1.4 Insofar as this Agreement, a Scope of Work or a PSA obliges any party to this Agreement to negotiate, take action or to do something, that party shall conduct such communications, negotiations, take such action or do such thing in good faith acting professionally and, in the case of Fujifilm, using Commercially Reasonable Efforts to achieve the result contemplated in this Agreement. There shall be a general obligation on the parties to act in good faith and with professionalism in relation to the matters contemplated in this Agreement.

1.5 In the case of conflict or ambiguity between terms of the main body of this Agreement, any Schedule to this Agreement or any other terms in any Scope of Work or PSA, the order of priority shall be as follows: (i) the main body of the Agreement; (ii) the Schedules to the Agreement; and (iii) the main body of the Scope of Work or PSA (as applicable) unless a Scope of Work or PSA specifically varies a provision of the Agreement or a Schedule to the Agreement by reference to the provision it is amending in which case the Scope of Work or PSA (as applicable) shall take precedence in that instance.

1.6 In the case of conflict or ambiguity between the terms of this Agreement, a PSA or any Scope of Work and the terms of the QA Documents, the terms of the QA Documents shall prevail solely in relation to cGMP quality matters subject to clause 9.10.

1.7 Where a defined term is used in clause 9 (Liability) it shall retain its meaning even when the entire word that is a defined term is in capitals.

1.8 Where a provision requires agreement, consent and/or approval of a party, such agreement, consent and/or approval, unless expressly stated otherwise, may not be unreasonably withheld, delayed or conditioned.

1.9 The parties agree that all Scopes of Work, PSAs, Changes, notices and other documents or correspondence under this Agreement and the Quality Agreement shall be in English.

2. APPOINTMENT OF FUJIFILM AND SCOPE OF SERVICES

2.1 Appointment

2.1.1 This Agreement establishes the general terms and conditions applicable to Fujifilm's performance of each Program for the Customer and is structured so that a separate, numbered, Scope of Work (or in some cases multiple Scope of Works) and/or a PSA shall be entered into by the parties for the provision of a Program. A purchase order which is issued by the Customer shall be treated exclusively as an ordering mechanism (in accordance with Schedule 2) and a finance tool for the purposes of raising invoices and any terms set out, or referred to, on such purchase order shall have no effect and shall not bind Fujifilm.

2.1.2 The provisions of this Agreement shall apply to each Scope of Work and each PSA and no Scope of Work or PSA shall be effective or binding on any party until it has been signed by an authorized representative of each contracting party.

2.1.3 Nothing in this Agreement, any Scope of Work or any PSA shall oblige any party to enter into any Scope of Work or PSA and each Scope of Work or PSA constitutes a separate contract.

2.2 Scope of the Services

2.2.1 The scope of this Agreement covers research and development services (including initial technical transfer activities) through to commercial supply of Product.

2.2.2 The parties may enter into a Scope of Work (or any number of Scopes of Work) for R&D Services and a PSA for Commercial Manufacturing Services. Each Scope of Work and each PSA shall nonetheless clearly identify whether the Fujifilm Services to be provided are R&D Services or Commercial Manufacturing Services.

2.3 Forecasting and Orders

2.3.1 In respect of a PSA for Commercial Manufacturing Services:

(a) the Customer's capacity requirements will be forecasted in accordance with Schedule 2 unless expressly agreed otherwise in the relevant PSA;

(b) the Customer shall place Orders for Products pursuant to that PSA in accordance with Schedule 2. Any Order placed will be subject to this Agreement and the applicable PSA and any standard terms of the Customer referenced in any such Order shall not apply.

2.3.2 The Customer shall enter into Scope(s) of Work in respect of R&D Services and the Scope of Work shall detail the Customer's requirements, including the forecasting details associated with that Scope of Work. For the avoidance of doubt Schedule 2 does not apply to R&D Services.

3. **TERM**

3.1 This Agreement shall come into force on the Effective Date and shall continue until terminated by either party in accordance with the terms of this Agreement.

3.2 A party may terminate this Agreement upon giving [***] ([***]) [***] written notice to the others, provided that there are no uncompleted PSA(s) or Scope of Work(s) existing at the date such notice is given.

3.3 Each Scope of Work will take effect from the SoW Effective Date and shall continue until the earlier of:

3.3.1 the date specified in the Scope of Work, or if no such date is specified, the date the Program, or part of the Program referred to in the Scope of Work is completed; or

3.3.2 termination of this Agreement or the relevant Scope of Work in accordance with the terms of this Agreement.

3.4 Each PSA will take effect from the PSA Effective Date and shall continue until the earlier of:

3.4.1 expiry of the term stated therein (which the parties agree shall not be less than [***]); or

3.4.2 termination of this Agreement or the relevant PSA in accordance with the terms of this Agreement.

4. **PERFORMANCE OF PROGRAM**

4.1 Fujifilm shall carry out each Program, or parts of each Program, using Commercially Reasonable Efforts in accordance with:

4.1.1 the terms of this Agreement and any PSA or Scope of Work (as applicable);

4.1.2 Applicable Laws;

4.1.3 the Quality Agreement and cGMP (in both cases when applicable); and

4.1.4 the Process Specification for the applicable cGMP Batch (if any).

4.2 The parties agree that it shall not be considered a breach of this Agreement, any PSA, or any Scope(s) of Work, by Fujifilm if an objective of a Program is not achieved provided that Fujifilm has complied with its obligations set out in clause 4.1. Notwithstanding any contrary provisions in this Agreement, any PSA or any Scope(s) of Work, the parties acknowledge and agree that the services to be performed during the Program prior to the Commercial Trigger (together with any SoWs for R&D Services after the Commercial Trigger) are by their nature developmental and Fujifilm cannot (and consequently does not) guarantee to the Customer the achievement of a successful outcome for the Program, production of Conforming Batches or production of a specified volume of Product.

4.3 Each Scope of Work and each PSA contains assumptions on which Fujifilm's ability to perform a Program depends. If an assumption set out in the Scope of Work or PSA proves to be incorrect or actual circumstances differ from an assumption (including if such assumption cannot be met at such time as Fujifilm reasonably requires to enable it to perform its obligations) then the parties shall agree a Change to account for the change in assumption.

4.4 The Customer shall:

4.4.1 promptly provide the Customer Deliverables set out in the SoW or PSA (as applicable);

4.4.2 meet all its obligations and responsibilities under this Agreement, any PSA(s) and Scopes of Work (including, in particular, any Customer dependencies set out in a PSA or Scope of Work) and the Quality Agreement;

4.4.3 comply with Applicable Laws; and

4.4.4 promptly provide all assistance, information, and advice and do all acts which Fujifilm may reasonably request to enable Fujifilm to comply with its obligations and responsibilities under this Agreement, any PSA, any Scope of Work and the Quality Agreement.

4.5 In the case of Commercial Manufacturing Services, Fujifilm shall be entitled, but not obliged, to manufacture more Batches than are ordered by the Customer to create a stock of Product to satisfy Customer's Orders placed in accordance with Schedule 2 provided that Product that is delivered to Customer must have that number of [***] specified in the applicable PSA remaining before its Shelf Life expires.

5. QUALITY AND REGULATORY MATTERS

5.1 Quality Agreement

5.1.1 The Parties shall use Commercially Reasonable Efforts to ensure that the applicable Quality Agreement will be drafted and executed prior to the Effective Date).

5.1.2 The Customer acknowledges that Fujifilm shall not commence any cGMP activity until the Quality Agreement is executed by both parties.

5.2 Regulatory Assistance

5.2.1 The Customer shall provide Fujifilm with a copy of the Customer's Chemistry, Manufacturing and Controls section of any submission to a Regulatory Authority supporting the Customer's regulatory filing activities for the applicable Drug Product or Process which relates to or contains information about the Process; the Facility (including Fujifilm equipment); the Fujifilm Services and/or the Ancillary Services ("**CMC Section**") in accordance with the Quality Agreement. The Customer shall provide Fujifilm the opportunity to review and comment on a CMC Section that relates to any information regarding or impacting Fujifilm, or any information provided to the Customer by Fujifilm related to or in accordance with the Quality Agreement. If the CMC Section(s) is/are submitted without Fujifilm's prior approval, the Customer shall be solely responsible for the CMC Section's accuracy. Customer acknowledges and agrees that if the CMC Section is not accurate, Fujifilm may not be able to progress the Program due to actions by Regulatory Authorities, and a Delay may result.

5.2.2 During a Program the Customer may request assistance from Fujifilm in respect of the CMC Section, subject to payment by the Customer of a reasonable commercial rate for such assistance and Fujifilm's reasonable expenses. However, no advice or assistance given by Fujifilm shall be deemed to be or construed as a guarantee that a Drug Product will receive regulatory approval.

5.2.3 Fujifilm will provide one electronic (PDF) copy of any documents which may be reasonably required by the Customer in support of its regulatory filing activities. If the Customer requires copies of the laboratory documents, provision of these will be subject to discussion and agreement by the parties and agreement of an additional fee associated with copying.

5.2.4 The Customer shall have the right and responsibility for determining regulatory strategy, decisions and actions relating to each Program and any Product and/or Drug Product subject to clause 5.2.5 and provided that Fujifilm shall have the right and responsibility for determining regulatory strategy, decisions and actions to the extent relating to:

(c) the Facility (including in particular utilities and equipment);

(d) Fujifilm's quality systems, policies and internal procedures;

(e) any requirement imposed on Fujifilm by a Regulatory Authority; or

(f) any other commitments made by Fujifilm prior to the SoW Effective Date of the first SoW in a Program or PSA Effective Date of the first PSA in the Program (as applicable),

(each a "**Fujifilm Regulatory Responsibility**").

5.2.5 The Customer acknowledges that Fujifilm Quality Assurance team reserves the right to Disposition Product to the Customer in accordance with the Quality Agreement.

5.2.6 The Customer shall not make any change to its regulatory filings, including its Investigational New Drug application, which may have an impact on any Fujifilm Regulatory Responsibility without consultation and opportunity to review and comment by Fujifilm.

5.3 No Debarment.

5.3.1 Each party represents and warrants to the other that neither it nor any of its officers, directors, or its employees performing services under this Agreement has been debarred, or convicted of a crime which could lead to debarment, under the Generic Drug Enforcement Act of 1992, 21 United States Code §§335(a) and (b).

6. **CONFORMING BATCHES AND NON-CONFORMING BATCHES**

6.1 Each cGMP Batch will be determined to be a Conforming Batch or a Non-Conforming Batch.

6.2 Deviations will be handled in accordance with the Quality Agreement and, for the avoidance of doubt, the Customer acknowledges that the occurrence of a Deviation does not automatically mean that a Batch is a Non-Conforming Batch.

6.3 In respect of Conforming Batches, Fujifilm will complete Disposition, issue a certificate of analysis, and a Certificate of Compliance. The provisions of clauses 1.1 to 6.5.1 shall apply to Non-Conforming Batches only.

6.4 If a Batch is a Non-Conforming Batch and the cause of that Batch being a Non-Conforming Batch is not a failure by Fujifilm to comply with clause 4.1 then the Customer shall pay the Charges relating to the Non-Conforming Batch in full and the relevant manufacturing stage, Disposition and all related and ancillary activities shall be deemed to have been completed under the Scope of Work or PSA (as applicable). Any further work in relation to the Non-Conforming Batch (such as analysis of the Batch) or manufacture of a replacement cGMP Batch shall be carried out at a time and price to be agreed in writing by the parties in a Change.

6.5 If a Batch is a Non-Conforming Batch and the cause of the Batch being a Non-Conforming Batch is a failure by Fujifilm to comply with clause 4.1 then:

6.5.1 if the Non-Conforming Batch is produced prior to the Commercial Trigger, Fujifilm shall use Commercially Reasonable Efforts to manufacture a replacement cGMP Batch ("**Replacement Batch**") as soon as is reasonably practicable ensuring that the Customer is treated equitably in any asset re-scheduling that may be undertaken to accommodate this. In these circumstances the Customer shall pay for (i) all Charges with respect to the original Non-Conforming Batch in accordance with the SoW (save that any installments of the Charges which are not due to be invoiced until a trigger which occurs after the date that the Non-Conforming Batch is determined to be a Non-Conforming Batch shall be invoiced instead on completion of the relevant trigger in relation to the Replacement Batch, for example, vial thaw or delivery) incurred during the manufacture of the Replacement Batch; and (ii) the Ancillary Charges for the Ancillary Services provided in relation to the Replacement Batch shall be payable by the Customer but for the avoidance of doubt the Fujifilm Services provided in relation to the Replacement Batch shall be free of charge; and

6.5.2 if the Non-Conforming Batch is produced after the Commercial Trigger then unless clause 6.5.3 applies, Fujifilm shall manufacture a replacement cGMP Batch (also a "**Replacement Batch**") so as to satisfy the affected Order and shall use Commercially Reasonable Efforts to manufacture that Replacement Batch as soon as is reasonably practicable ensuring that the Customer is treated equitably in any asset re-scheduling that may be undertaken to accommodate this. In these circumstances the Customer shall pay for (i) all Charges in respect of the original Non-Conforming Batch in accordance with this Agreement save that any instalment of the Charges which have not yet been invoiced will be delayed until the payment trigger for that payment (for example vial thaw or delivery) occurs during the manufacture of the Replacement Batch; and (ii) [***] of the Ancillary Charges for the Ancillary Services provided in relation to the Replacement Batch shall be payable by the Customer but for the avoidance of doubt the Fujifilm Services provided and [***] of the Ancillary Charges in relation to the Replacement Batch shall be free of charge; and

6.5.3 if the Non-Conforming Batch is produced after the Commercial Trigger and is part of a campaign of batches where such campaign commences more than [***] after completion of the last cGMP Batch manufactured by Fujifilm then clause 6.5.1 will apply.

6.5.4 In respect of any Program in which an Engineering Batch is not executed prior to manufacture of the first cGMP Batch in such Program, if the first cGMP Batch is a Non-Conforming Batch, it will be deemed that the cause of such Batch being a Non-Conforming Batch is not a failure of Fujifilm to comply with clause 4.1 and clause 6.4 shall apply, unless the cause of the cGMP Batch being a Non-Conforming Batch is Fujifilm's Gross Negligence or Wilful Misconduct, in which case clause 6.5 shall apply.

6.6 If the Customer requests delivery of a Non-Conforming Batch, the parties shall agree in writing (in a Change) on fair consideration payable for that Non-Conforming Batch. Fujifilm agrees to deliver a Non-Conforming Batch to the Customer on the express condition that it (i) will not be used for human or clinical trials; (ii) will be labeled as "Not for Human Use"; and (iii) is subject to the Customer's indemnity given under clause 9.6.

6.7 In the event of a Latent Defect, Customer shall notify Fujifilm of such Latent Defect using Fujifilm's quality complaints procedure as set out in the Quality Agreement no later than the earlier of: (a) [***] ([***]) Business Days from the date Customer becomes aware of such Latent Defect, or (b) or [***] ([***]) [***] following the delivery date. The Parties shall cooperate to identify the cause of such Latent Defect. If the sole cause of the Latent Defect resulted Fujifilm's failure to comply with clause 4.1.1 of the Agreement, clause 6.5 shall apply. For clarity, in the event the Latent Defect is caused by: (a) inherent Product instability, or (b) subsequent Customer actions, including without limitation, handling, shipping and storage of Product, clause 6.4 shall apply.

6.8 If the parties cannot agree if a Batch is a Conforming Batch or a Non-Conforming Batch and/or if the cause of a Batch being a Non-Conforming Batch is not agreed by the parties, then this clause 6.7 shall apply:

6.8.1 the parties will first exhaust the investigation/resolution options set out in the Quality Agreement including reference to the Material Review Board ("MRB") under the Quality Agreement and transparent disclosure of all applicable reports and analysis on which their respect opinion is based;

6.8.2 if the MRB is unable to resolve this matter then the documentation related to the applicable Batch will be reviewed by an independent cGMP consultant acceptable to both parties (acting reasonably). The result of such independent review will be binding for both parties solely for the purpose of determining whether the Batch is a Non-Conforming Batch and/or if a Non-Conforming Batch is caused by a failure by Fujifilm to comply with clause 4.1;

6.8.3 if the independent cGMP consultant finds that the Batch is not a Non-Conforming Batch or that the Non-Conforming Batch was not caused by a failure by Fujifilm to comply with clause 4.1, the Customer will pay Fujifilm for the Batch in question in accordance with clause 1.1 plus the reasonable cost to Fujifilm of the investigation;

6.8.4 if the independent cGMP consultant finds that the Batch is a Non-Conforming Batch and that the Non-Conforming Batch is caused by a failure by Fujifilm to comply with clause 4.1, the remedial procedure set out in clause 6.5 will be applied.

7. DELIVERY, TITLE AND RISK

7.1 Delivery by Fujifilm to the Customer, or the Customer's designee, of any material in connection with a Program including any quantity of Product manufactured during the Program, any Process-Specific Equipment and/or Process-Specific Consumables and return of any samples and cell lines supplied by the Customer ("**Materials**") will be made Ex Works the Facility (Incoterms 2020) and clauses 7.2 to 7.6 shall apply to such Materials. Fujifilm shall package the relevant Materials ready for shipment in accordance with the Customer's reasonable instructions.

7.2 Delivery of Materials will be deemed to be complete on the date which Fujifilm makes the Materials available for collection by the Customer (which is the point of delivery as set forth in Ex Works (Incoterms 2020)) following notification, of at least [***], by Fujifilm to the Customer that it will make those Materials available for collection (the "**Delivery Date**") in accordance with an indicative delivery schedule which shall be agreed by the parties' Program teams in advance. For the avoidance of doubt, and unless otherwise expressly agreed by the parties in writing, Fujifilm will not make a cGMP Batch available for collection by the Customer until both: (a) Disposition is complete; and (b) the Customer's quality assurance team has approved such Product for release in a written notice, following conduct of Customer's final disposition and release activities (including any release testing required; provided that such final disposition and release must be completed by Customer within [***] of Fujifilm first making available to Customer all production instruction and analytical records relating to the manufacture of such Product, together with the results of any testing of such Product (collectively, the "**Disposition Documentation**"). For the avoidance of doubt, Materials for which a licence is required under clause 10.3 will not be made available for collection by the Customer until a licence has been signed by the parties.

7.3 If the Customer fails to collect Materials within [***] of the Delivery Date, Fujifilm will issue a further notice to the Customer specifying that the Materials will either be moved to a third party storage facility or destroyed if they are not collected within [***] from the date of the notice. On or after the date [***] from the date of the notice, if Customer has not collected the Materials, Fujifilm may move or destroy the Materials at the Customer's risk and expense provided that prior to moving or destroying such Materials Fujifilm has issued a further notice to Customer warning that the Materials will either be moved to a third party storage facility or destroyed if they are not collected, giving Customer at least [***] to collect the Materials (such period ending on or after the end of the original [***] period).

7.4 Risk in Materials shall pass to the Customer on the Delivery Date; save for risk in (a) Process-Specific-Equipment or Process-Specific Consumables in relation to which risk shall pass as set forth in clause 7.6 and (b) Materials for which a license is required under clause 10.3 in relation to which risk shall pass on the date on which Fujifilm notifies the Customer it would have made the Materials available for collection if a license had been signed by the parties.

7.5 Title to the Product shall pass to the Customer on the Delivery Date.

7.6 Title to, and risk in, the Process-Specific Equipment and/or Process-Specific Consumables purchased by the Customer in accordance with Schedule 1 shall pass to the Customer on the earlier of (a) when Fujifilm has received payment in full (in cash or cleared funds) for such items in accordance with paragraph 3.1 of Schedule 1 or (b) the Delivery Date.

7.7 From time to time Fujifilm may agree to store Materials (including intermediate Product for future processing) for Customer. If Fujifilm agrees to store Materials the parties will enter into a storage agreement on Fujifilm's standard terms.

7.8 Delivery of any materials which the Customer is required to supply to Fujifilm pursuant to a SoW or any PSA shall be delivered to Fujifilm DDP, the Facility (Incoterms 2020). Risk in those materials remains with the Customer.

8. **PRICE AND PAYMENT**

8.1 Under this Agreement, and the relevant Scope(s) of Work and/or PSA(s), the Customer appoints Fujifilm to carry out services concerning the, testing, manufacture and Disposition of the Product by Fujifilm under each Program. The Charges relate specifically to those services; and are not in consideration of the supply of any material (including Product) which Fujifilm may produce as a consequence of the performance of those services.

8.2 The Customer shall pay to Fujifilm for each Program:

8.2.1 the Batch Fee(s);

8.2.2 the fees for the Fujifilm Services (other than the Batch Fee(s)) as set out in the relevant Scope(s) of Work and PSA(s);

8.2.3 the fees for Ancillary Services in accordance with Schedule 1 (the " **Ancillary Charges**"); and

the Annual Service Fee in respect of Commercial Manufacturing Services in accordance with Schedule 1, together the "**Charges**".

8.3 Fujifilm may invoice the Customer for the Charges in respect of each Program in accordance with the terms set out in the Scope of Work and/or PSA (as applicable) and Schedule 1.

8.4 The Customer shall pay each invoice issued to it by Fujifilm within [***] of the date of invoice, in full and in cleared funds in the currency specified in the SoW or PSA (as applicable) by electronic transfer to the financial institution specified in the relevant invoice.

8.5 The Charges are exclusive of any Tax which may apply and which shall be payable by the Customer to Fujifilm at the rate prescribed by law.

8.6 If there is a change in the rate of Tax payable or in the Tax treatment of some or all of the services provided by Fujifilm or the Product, e.g. due to a change of law or practice or interpretation of the existing legislation or revised determination of a relevant tax legislation or tax practice, then the Customer agrees that Fujifilm shall be entitled, where Tax is imposed on a supply by Fujifilm under or in connection with this Agreement, to invoice the Customer (in a valid Tax invoice) for a sum equal to the amount of the Tax which becomes due on that supply and any fees and/or interest which is being levied on Fujifilm in relation to the outstanding sums and/or non-payment. The Customer shall pay those invoices in accordance with clause 8.4.

8.7 The Customer shall:

8.7.1 be responsible for the collection, remittance and payment of any or all Taxes, in respect of the purchase, importation, exportation, sale or other distribution of any materials delivered to it by Fujifilm in connection with a Program; and

8.7.2 make all payments under this Agreement without withholding or deduction of, or in respect of, any Tax unless required by law. If withholding tax is deducted then the Customer will provide all documentation required to enable Fujifilm to recover the tax withheld.

8.8 Without prejudice to any other right or remedy that it may have, if the Customer fails to pay any sum to Fujifilm on the due date for payment:

8.8.1 the Customer shall pay interest on the overdue amount at the rate of [***] per [***]. Such interest shall be payable in respect of the period from the due date until actual payment of the overdue amount (whether before or after judgment) in accordance with clause 8.4; and

8.8.2 (except where the Customer has complied with its obligations in clause 8.9 below) Fujifilm may notify the Customer that if it does not pay Fujifilm will suspend work on the Program, including, without limitation, delivery of Materials, in respect of which payment is overdue, and if payment is not made within [***] of such notice, Fujifilm may suspend such work until payment has been made in full.

8.9 If the Customer disputes the payment of any Charges or a part of them, the Customer shall:

8.9.1 notify Fujifilm of the disputed amount within [***] of its receipt of the invoice in which such disputed amount is included giving reasonable details of the dispute; and

8.9.2 pay the amount of Charges not in dispute in accordance with clause 8.4,

and the dispute shall be dealt with under the dispute resolution process set out in clause 16.

8.10 If the Customer fails to pay any sum which is not the subject of a bona fide dispute under clause 8.9 when the same is due in accordance with clause 8.4 then Fujifilm may elect, at its discretion, to treat such non-payment as a material breach of either the relevant SoW(s) or PSA(s) under clause 14.6.1 or a material breach of this Agreement under clause 14.2.1.

8.11 A party shall not be entitled to withhold, set off or reduce payment of any amounts payable under this Agreement by any amounts which it claims are owed to it by another party under this Agreement or any other agreement.

9. **LIABILITY**

9.1 Nothing in this Agreement limits or excludes the liability of any party to the other for any liability that is not permitted to be limited or excluded by law and clauses 9.2 to 9.7 are expressly agreed to be subject to this clause 9.1.

9.2 EXCEPT IN RESPECT OF BREACH BY FUJIFILM OF CLAUSE 12 (CONFIDENTIALITY) OR LIABILITY ARISING UNDER CLAUSE 11.1 (IPR INDEMNITY) AND SUBJECT ALWAYS TO CLAUSES 9.3, 9.6, 9.7, 9.8 AND 9.9, FUJIFILM'S TOTAL LIABILITY, WHETHER OR NOT ARISING PURSUANT TO AN INDEMNITY, IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY), MISREPRESENTATION, RESTITUTION OR OTHERWISE ARISING UNDER THIS AGREEMENT, A SCOPE OF WORK OR A PSA OR IN CONNECTION WITH THE PERFORMANCE OR CONTEMPLATED PERFORMANCE OF THIS AGREEMENT, A SCOPE OF WORK OR A PSA SHALL IN ALL CIRCUMSTANCES BE LIMITED AS FOLLOWS:

9.2.1 TO THE EXTENT THERE HAS BEEN NO GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY FUJFILM:

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WITH A NON-MANUFACTURING STAGE, FUJIFILM'S TOTAL LIABILITY SHALL BE LIMITED TO AN AMOUNT EQUAL TO THE CHARGES PAID BY CUSTOMER TO FUJIFILM FOR THE FUJIFILM SERVICES PERFORMED UNDER THAT NON-MANUFACTURING STAGE; AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WITH A MANUFACTURING STAGE (INCLUDING LIABLITY RELATING TO THE MANUFACTURE OF, OR FAILURE TO MANUFACTURE, A BATCH), FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED TO AN AMOUNT EQUAL TO THE BATCH FEE PAID BY CUSTOMER TO FUJIFILM UNDER THAT MANUFACTURING STAGE; OR

9.2.2 TO THE EXTENT THERE HAS BEEN GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY FUJFILM:

(a) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WITH A NON-MANUFACTURING STAGE, FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***] OF THE CHARGES PAID BY CUSTOMER TO FUJIFILM FOR THE FUJIFILM SERVICES PERFORMED UNDER THAT NON-MANUFACTURING STAGE; AND

(b) IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER OR IN CONNECTION WITH A MANUFACTURING STAGE, (INCLUDING LIABLITY RELATING TO THE MANUFACTURE OF, OR FAILURE TO MANUFACTURE, A BATCH), FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED TO AN AMOUNT EQUAL TO [***]% OF THE BATCH FEE PAID BY CUSTOMER TO FUJIFILM UNDER THAT MANUFACTURING STAGE; AND

9.2.3 IN RESPECT OF ANY AND ALL LIABILITY ARISING UNDER ANY SCOPE OF WORK OR PSA, FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED IN AGGREGATE PER CALENDAR YEAR TO AN AMOUNT EQUAL TO [***] OF THE CHARGES PAID BY CUSTOMER FOR FUJIFILM SERVICES IN RESPECT OF THAT SCOPE OF WORK OR PSA DURING THAT CALENDAR YEAR IN WHICH THE LIABLITY AROSE AND CLAUSES 9.2.1 AND 9.2.2 ARE SUBJECT TO THE AGGREGATE LIABILITY LIMITATION SET OUT IN THIS CLAUSE 9.2.3; AND

9.2.4 IN RESPECT OF ANY OTHER LIABILITY RELATING TO THIS AGREEMENT FALLING OUTSIDE THE SCOPE OF CLAUSES 9.2.1 AND 9.2.2, FUJIFILM'S TOTAL LIABILITY TO CUSTOMER SHALL BE LIMITED PER CALENDAR YEAR TO $[***] ([***]).

9.3 UNDER NO CIRCUMSTANCES SHALL FUJIFILM BE LIABLE, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), FOR BREACH OF STATUTORY DUTY OR OTHERWISE, ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR: LOSS OF PROFIT; LOSS OF BUSINESS; DEPLETION OF GOODWILL; LOSS OF ANTICIPATED SAVINGS; LOSS OR CORRUPTION OF DATA OR INFORMATION; OR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR PURE ECONOMIC LOSS, COSTS, DAMAGES, CHARGES OR EXPENSES, INCLUDING THE COSTS OF ANY RECALL OF THE PRODUCT OR DRUG PRODUCT.

9.4 Liability for Product and Drug Product: the Customer shall Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from the use or resale of the Product or the Drug Product or any other deliverable arising out of a Program except to the extent those Liabilities have arisen pursuant to the Gross Negligence or Willful Misconduct of Fujifilm in which case Fujifilm shall bear such Liabilities up to the amounts for which Fujifilm is liable to the Customer under clause 9.2.2 and the Customer's indemnity of Fujifilm under this clause 9.4 shall apply to any Liabilities arising thereafter.

9.5 Liability for the Process: the Customer shall Indemnify Fujifilm from and against all Liabilities arising from third party claims incurred by Fujifilm or its Affiliates arising out of or resulting from the use or operation of the Process (or any part of the Process) except to the extent that Fujifilm is liable under clause 11.1.

9.6 Liability for Non-Conforming Batches:

9.6.1 THE PROVISIONS OF CLAUSE 6 SHALL APPLY TO NON-CONFORMING BATCHES AND FUJIFILM SHALL HAVE NO LIABILITY IN RESPECT OF NON-CONFORMING BATCHES EXCEPT TO COMPLY WITH CLAUSE 6.

9.6.2 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER (WHETHER AS TO COMPLIANCE WITH CGMP OR OTHERWISE) IN RESPECT OF NON-CONFORMING BATCHES OR THE USE BY THE CUSTOMER OF NON-CONFORMING BATCHES.

9.6.3 If the Non-Conforming Batch is delivered to the Customer pursuant to clause 6, the Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from the use of that Non-Conforming Batch.

9.6.4 The Customer uses any material produced in a Non-Conforming Batch at its own risk and shall undertake such tests as are necessary in order to satisfy itself that such materials are fit for the purposes for which the Customer proposes to use such materials.

9.7 Liability for Demonstration and Engineering Batches

9.7.1 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER (WHETHER AS TO COMPLIANCE WITH CGMP OR OTHERWISE) IN RESPECT OF THE DEMONSTRATION BATCHES OR ENGINEERING BATCHES OR THE USE BY THE CUSTOMER OF AN ENGINEERING BATCH OR DEMONSTRATION BATCH.

9.7.2 FUJIFILM SHALL HAVE NO LIABILITY TO THE CUSTOMER IN CONNECTION WITH DEMONSTRATION BATCHES OR ENGINEERING BATCHES OR THE USE BY THE CUSTOMER OF THE DEMONSTRATION BATCHES OR ENGINEERING BATCHES.

9.7.3 The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of or resulting from the use of the Demonstration Batches or Engineering Batches.

9.7.4 The Customer uses any material produced in a Demonstration Batch or Engineering Batch at its own risk and shall undertake such tests as are necessary in order to satisfy itself that such materials are fit for the purposes for which the Customer proposes to use such materials. Customer expressly agrees that Product produced pursuant to a Demonstration Batch or an Engineering Batch is not suitable, and will not be used, for human consumption or use or in clinic trials.

9.8 FUJIFILM GIVES NO, AND DISCLAIMS ANY, WARRANTIES, UNDERTAKINGS OR SIMILAR TERMS WHATSOEVER IN RESPECT OF ANY ADVICE OR ASSISTANCE GIVEN BY FUJIFILM IN CONNECTION WITH THE USE OF THE PRODUCT IN OR AS A DRUG PRODUCT (INCLUDING ADVICE OR ASSISTANCE RELATED TO ANY REGULATORY APPROVAL).

9.9 ALL WARRANTIES, CONDITIONS AND OTHER TERMS, EXPRESS (OTHER THAN THOSE SET OUT IN THIS AGREEMENT) OR IMPLIED, STATUTORY, CUSTOMARY OR OTHERWISE WHICH BUT FOR THIS CLAUSE 9 WOULD OR MIGHT SUBSIST IN FAVOR OF THE CUSTOMER, ARE (TO THE FULLEST EXTENT PERMITTED BY LAW) EXCLUDED FROM THIS AGREEMENT INCLUDING, IN PARTICULAR, ANY IMPLIED WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR USE AND NON-INFRINGEMENT.

9.10 No claim for Liabilities incurred pursuant to the Quality Agreement may be made under the Quality Agreement by any party. Accordingly, performance of the Quality Agreement shall be deemed to be performance under the relevant SoW or PSA to which the Quality Agreement relates and as such any breach of the Quality Agreement shall be deemed to be a breach of the relevant SoW or PSA and all Liabilities shall be construed and limited in accordance with this clause 9.

9.11 If the parties enter into a Scope of Work for stability or analytical services subject to this Agreement, the parties agree that such services shall be incidental and it is therefore reasonable that such Scope of Work may contain lower limits on Fujifilm's Liability than are contained in this Agreement, in which case such limitation as set out in such Scope of Work shall apply to such Scope of Work.

9.12 Each party agrees to take all reasonable steps to mitigate any Liabilities that it may seek to claim from the other under or in connection with this Agreement including pursuant to any indemnity.

9.13 If a party is entitled to benefit from an indemnity (the " **Indemnified Party**") from another party (the "**Indemnifying Party**") in accordance with this Agreement (an "**Indemnity Claim**"), the Indemnified Party shall notify the Indemnifying Party in writing within [***] of identification of the Indemnity Claim (providing all necessary details), provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim and the Indemnifying Party shall at its own expense conduct all negotiations and any litigation arising in connection with the Indemnity Claim provided always that:

9.13.1 the Indemnifying Party shall consult the Indemnified Party on all substantive issues which arise during the conduct of such litigation and negotiations and shall take due and proper account of the interests of the Indemnified Party;

9.13.2 the Indemnifying Party shall not settle or compromise the Indemnity Claim without the Indemnified Party's prior written consent (not to be unreasonably withheld or delayed) and shall ensure that any settlement or compromise does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of the Indemnified Party;

9.13.3 the Indemnified Party shall not make any admissions or admit liability in relation to the Indemnity Claim or otherwise settle any Indemnity Claim without the written agreement of the Indemnifying Party; and

9.13.4 the Indemnified Party shall fully cooperate and assist the Indemnifying Party, at the Indemnifying Party's cost and expense, in relation to the Indemnity Claim (without limiting the extent of the Indemnity).

9.14 Each party shall maintain adequate insurance (which may be through self-insurance) to enable it to satisfy its Liabilities under this Agreement as they arise.

10. INTELLECTUAL PROPERTY

10.1 Subject to clause 10.2 neither party shall acquire any right, title or interest in the other party's Background IP.

10.2 The Customer grants to Fujifilm a royalty-free, non-transferable, revocable, and non-sublicensable worldwide license to use Customer's Background IP for the exclusive purpose of performance of each Program. Customer warrants that the use by Fujifilm (or its Authorized Third Parties) of Customer's Background IP in accordance with this clause 10.2 shall not infringe any third party's Intellectual Property Rights.

10.3 Fujifilm shall not be obliged to deliver any materials (including any cell bank or cell paste) comprising Fujifilm Expression Technology unless and until a license is granted in writing on terms to be agreed under the relevant Background IP. Fujifilm shall be entitled to charge the Customer for storage of any such materials which would have been delivered under clause 7.2 if a license had been granted under this clause 10.3 until the time that such license is granted. Customer acknowledges that storage may be at a third party storage facility unless Fujifilm and Customer have agreed in writing otherwise.

10.4 All title to and all rights and interest in any Customer Foreground IP shall vest in Customer. Fujifilm hereby assigns to the Customer all title to and all rights and interest it owns in any Customer Foreground IP.

10.5 All title to and all rights and interest in any Fujifilm Foreground IP shall vest in Fujifilm. The Customer hereby assigns to Fujifilm all title to and all rights and interest it owns in any Fujifilm Foreground IP.

10.6 If requested to do so by the other party, each party shall at the expense of the requesting party execute all documents and do all such further acts as the requesting party may reasonably require to perfect the assignment under clause 10.4 or 10.5.

10.7 Fujifilm grants to Customer a royalty free, non-exclusive, worldwide license to use the Fujifilm Foreground IP for the exclusive purpose of manufacturing the Product.

11. INTELLECTUAL PROPERTY INDEMNITY

11.1 Fujifilm shall fully Indemnify the Customer from and against all Liabilities incurred by the Customer or its Affiliates arising out of any third party claim that Fujifilm's use of Fujifilm's Background IP in performing a Program infringes such third party's Intellectual Property Rights.

11.2 The Customer shall fully Indemnify Fujifilm from and against all Liabilities incurred by Fujifilm or its Affiliates arising out of any third party claim that:

11.2.1 Fujifilm's use of (i) materials provided by the Customer to Fujifilm or (ii) Customer's Intellectual Property Rights, in accordance with this Agreement; or

(excluding Liabilities in relation to which Fujifilm Indemnifies the Customer pursuant to clause 11.1) the development or manufacture of the Product and/or any other deliverables which are an output of a Program or the use of the Process in accordance with this Agreement, infringes such third party's Intellectual Property Rights.

11.3 If a third party claim is made in accordance with clause 11.1 or 11.2 then the Indemnified Party may require the Indemnifying Party to prove that it has adequate financial means to pay out under the indemnity provisions provided for in those clauses (for example by way of set aside capital or insurance). If the Indemnifying Party cannot so prove it has the financial standing to meet its obligations with respect to the Indemnities under the applicable clause then the Indemnified Party has the option to terminate this Agreement on written notice. If Fujifilm exercises its option to terminate under this clause 11.3 then (without prejudice to the survival of the relevant Indemnity obligations) such termination shall be treated as a termination under clause 14.3.

12. **CONFIDENTIALITY**

12.1 Each party (the "**Receiving Party**") agrees with the other (the " **Disclosing Party**"):

12.1.1 to keep the Disclosing Party's Confidential Information confidential;

12.1.2 not to access or use the Disclosing Party's Confidential Information save for the purposes of:

(a) complying with its obligations under this Agreement, each SoW and/or each PSA;

(b) complying with, or exercising its rights under, any confidentiality disclosure agreement then in force between the Parties; or

(c) undertaking activity by and between the parties to enable the parties to explore a new business opportunity (" **New Opportunity**");

12.1.3 not to disclose the Disclosing Party's Confidential Information to a third party other than to the Receiving Party's:

(a) Affiliates;

(b) officers and employees and those of its Affiliates that need to know the Confidential Information for the purpose of performing its obligations under this Agreement, a PSA, a SoW, or in relation to a New Opportunity;

(c) contractors and sub-contractors, professional advisers, consultants, and agents and those of its Affiliates who are engaged to advise that party in connection with a Program or this Agreement or in relation to a New Opportunity; and

(d) any other person to whom the Disclosing Party agrees in writing that Confidential Information may be disclosed in connection with a Program,

the "**Authorized Third Parties**".

12.2 The parties acknowledge and agree that the Disclosing Party Authorized Third Parties may disclose its Confidential Information directly to the Receiving Party or its Authorized Third Parties and that such disclosure shall be governed by this clause 12. The Receiving Party shall procure that each of the Authorized Third Parties keeps the Disclosing Party's Confidential Information confidential in accordance with this clause 12 and shall remain primarily liable to the Disclosing Party for any act or omission of any of the Authorized Third Parties.

12.3 The Receiving Party shall within [***] of receipt of the Disclosing Party's written request (including after termination of this Agreement, any SoW and/or any PSA):

12.3.1 deliver up to the Disclosing Party all items and copies of all or any Confidential Information of the Disclosing Party;

12.3.2 expunge and/or make irretrievable all Confidential Information of the Disclosing Party from any computer or other similar device in which it is stored and, if further requested, certify in writing signed by an authorized representative that it has done the same (provided that this clause 12.3.2 shall not apply to automatically archived electronic files or electronic back-ups made in the ordinary course of business, on secured central servers, which cannot reasonably be deleted and such electronic files shall be retained subject to the obligations of confidence set out in this clause 12); and

12.3.3 destroy all hard copies of notes, analyses or memoranda containing the Disclosing Party's Confidential Information (and, if further requested, certify in writing signed by an authorized representative that it has done the same)

provided that the Receiving Party shall be entitled to retain copies of the Confidential Information to enable it to monitor its obligations under this Agreement or which is required to be maintained by Applicable Laws or a Regulatory Authority subject always to the obligations of confidence under this Agreement.

12.4 Confidential Information shall not include information, which:

12.4.1 is, or becomes, generally available to the public other than as a direct or indirect result of the information being disclosed by the Receiving Party or its Authorized Third Parties in breach of this Agreement (except that any compilation of otherwise public information in a form not publicly known shall still be treated as Confidential Information);

12.4.2 was available to the Receiving Party on a non-confidential basis prior to disclosure by the Disclosing Party;

12.4.3 was, is, or becomes available to the Receiving Party on a non-confidential basis from a person who, to the Receiving Party's knowledge, is not under any confidentiality obligation in respect of that information;

12.4.4 was lawfully in the possession of the Receiving Party before the information was disclosed by the Disclosing Party as demonstrated by records where such demonstration is reasonably feasible;

12.4.5 is developed by or for the Receiving Party independently of the information disclosed by the Disclosing Party; or

12.4.6 the Disclosing Party and the Receiving Party agree in writing is not confidential.

12.5 Receiving Party may disclose Confidential Information of Disclosing Party when necessarily required pursuant to a statutory or regulatory obligation (including any regulatory approvals for the Product in any or all jurisdictions), but then only to the extent of such required disclosure and save that the Receiving Party shall, to the extent it is lawful to do so, give prompt notice to the Disclosing Party of any such potential disclosure and allow the Disclosing Party a reasonable opportunity to limit such disclosure.

12.6 Customer may use and disclose Confidential Information of Fujifilm solely to the extent necessary in communications with existing or prospective Customer's investors, sub-licensees or commercial partners provided that: (a) such recipients are under obligations of confidentiality obligations at least as restrictive as the terms of this clause 12; (b) none of the financial terms of the Agreement, a SoW or a PSA or any proposals are disclosed to any such investor, sublicensee or commercial partner without the prior written consent of Fujifilm; (c) no disclosures are made to contract development and/or manufacturing organizations in the biopharmaceutical industry without Fujifilm's prior written consent; (d) no disclosures are made with respect to information identified as being confidential information of a third party; and (e) such recipients are treated as Authorized Third Parties for the purposes of clause 12.2. Additionally, Customer shall notify Fujifilm of any disclosure to any investors, sub-licensees or commercial partners, including the name of the recipient and date and nature of disclosure.

13. **CHANGE**

13.1 Subject to clause 13.2, if a party wishes to change (" **Change**") any aspect of this Agreement, any PSA or any Scope of Work (including if additional or different work is requested or required such as the production of a different number of Batches or if such work is required to be carried out at a different time or if actual circumstances differ from the assumptions set out in a PSA or Scope of Work (including if such assumptions cannot be met at all or in a timely fashion)) then Fujifilm shall draft a Change document using its standard format for that Change and the Change shall not be effective until the applicable Change document (the "**Change Order**") is signed by each party.

13.2 It is acknowledged that there are greater limits on what can be changed in respect of a PSA for Commercial Manufacturing Services, but notwithstanding this, if there is a change to Applicable Law which comes into effect after the Effective Date that adversely affects, or is likely to adversely affect, production of Product by the Process when conducted in accordance with Fujifilm's standard operating procedures or methods, and within the declared constraints of the Facility then the parties will enter into a Change to accommodate that change of Applicable Law; the cost of which shall be allocated as follows:

13.2.1 if the change to Applicable Law specifically relates to the Product or Process then the Customer will be liable for the costs of the Change; and

13.2.2 if the change to Applicable Law relates to the Facility as it is operated by Fujifilm across its customer base or the general commercial activities carried out by Fujifilm then Fujifilm will be liable for the costs of the Change.

13.3 If the parties are unable to agree the terms of a Change and the dispute resolution process set out in clause 16 has been unsuccessfully exhausted, either party may terminate any affected Scope of Work (or part of it) or PSA (or part of it) (as applicable), Order (or part of it), or this Agreement by giving written notice to the other party if either party reasonably believes that it will be unable to carry out and complete such Scope of Work or Order or PSA (as applicable) in accordance with this Agreement or any future Order (as the case may be) due to the change of Applicable Law. However, any termination or cancellation made pursuant to this clause shall remain subject to all termination, cancellation or other fees provided for in this Agreement, including Batch Cancellation fees. For the sake of clarity, in the case of Commercial Manufacturing Services, Batches delivered or to be delivered as part of the Commercial Manufacturing Services are not cancellable and must be paid in full as stated in this Agreement. Likewise, termination of a PSA pursuant to this clause shall be governed in accordance with clause 14 of this Agreement.

14. **DELAY, CANCELLATION, TERMINATION AND CONSEQUENCES**

14.1 Delay:

14.1.1 If the Customer either causes or requests a delay to any Stage; Stages; or a Program as a whole and that delay prevents, or will prevent, Fujifilm from:

(a) during the R&D Services: performing a manufacturing stage or a Program as a whole in accordance with the Program Plan; or

(b) during the Commercial Manufacturing Services: manufacturing commercial Batches by the forecast date,

in each case, a "**Delay**", and the parties cannot agree a Change to accommodate that Delay; then that Delay will be treated as a termination for convenience by the Customer under clause 14.3 and the parties agree:

(c) in the case of a Batch produced as part of the Commercial Manufacturing Services, entitlement to that Batch does not carry forward to a subsequent Production Year if a Change cannot be agreed that results in the Batch being produced in the same Production Year as it was forecast; and

14.1.2 any Batch Cancellation Fee payable shall be calculated by reference to the date on which notice was given by the Customer in relation to the Delay if such notice is given, or the date on which the Delay becomes apparent to Fujifilm. Notwithstanding anything to the contrary in this Agreement, any applicable Scope of Work or any applicable PSA, in the event that, despite Fujifilm having exercised reasonable efforts to procure all necessary Consumables, such Consumables are not available in the quantities or at the time as may be required to manufacture a Batch for Customer pursuant to Fujifilm's current asset plan, Fujifilm's obligation to manufacture and deliver such Batch, and Customer's obligation to take delivery and pay for such Batch, shall in each case be delayed until such time as sufficient Consumables are available for the manufacture of such Batch ("**Consumables Delay**"). The Customer agrees that:

(a) it will use reasonable efforts to assist Fujifilm to procure Consumables that are subject to a Consumables Delay (which may include agreeing to allow Fujifilm to procure those Consumables from an alternative supplier); and

(b) if it requires Fujifilm to take specified action to mitigate a potential Consumables Delay and this action of itself causes a Delay then clause 14.1.1 will apply; and

(c) Consumables which Customer agrees to provide to Fujifilm under a SoW or a PSA are excluded from the definition of Consumables Delay and will be subject to clause 14.1.1.

14.1.3 The parties' Program teams shall mutually agree on the new manufacturing schedule for any Batches affected by a Consumables Delay, provided that Fujifilm shall use its Commercially Reasonably Efforts to make available sufficient slots for the manufacture of such Batches as soon as reasonably possible ensuring that the Customer is treated equitably in any asset re-scheduling that may be undertaken to accommodate this.

14.2 Termination of this Agreement as a whole

14.2.1 Fujifilm or the Customer shall be entitled to terminate this Agreement (and all Scope of Works and PSAs made under it, together with in the case of Commercial Manufacturing Services any Orders made under the applicable PSA(s)) immediately upon giving notice to the other if:

(a) the other party commits a material breach of clauses 8.4, 9.14, 12, 19 and such breach:

(b) is not capable of remedy (a breach shall be considered capable of remedy if the party in breach can comply with the provision in question in all respects other than as to time of performance); or

(c) is capable of remedy, and the breaching party fails to remedy the breach within a reasonable period after receipt of notice giving full particulars of the breach and requiring it to be remedied, provided, however, that such cure period shall be suspended during any time that a party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to clause 16;

(d) the other party takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;

(e) the other party is reasonably determined by the terminating party to be in material breach of [***] ([***]) or more contracts (including any Scopes of Work or PSAs) it has entered into with the terminating party; or

(f) the other party or the person controlling the other party has a change in control and the new controlling entity is reasonably considered by the party giving notice either to be its direct competitor or not to have reasonable financial creditworthiness.

14.3 Termination by the Customer for Convenience

14.3.1 The Customer may cancel one or more Non-Manufacturing Stage(s) intended to be delivered as part of R&D Services for convenience by giving written notice to Fujifilm in which case:

(a) the cancelled Non-Manufacturing Stage(s) shall terminate but in all other respects the SoW shall continue in full force; and

(b) the Customer shall pay Fujifilm the Charges that are due for the Fujifilm Services that have been performed and [***] of the Charges for the Fujifilm Services that have not yet been performed in the cancelled Non-Manufacturing Stage(s) plus (i) any Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion of any Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

(c) in the event Customer terminates this Agreement or a Program where there are only Non-Manufacturing Stages contracted, this clause 14.3.1 shall apply when determining cancellation fees.

14.3.2 The Customer may cancel one or more manufacturing stage(s) delivered as part of the R&D Services (i.e. manufacturing stage(s) that are not part of the Commercial Manufacturing Services) for convenience by giving written notice to Fujifilm in which case:

(a) that manufacturing stage shall terminate but in all other respects the SoW shall continue in full force;

(b) the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed, the relevant Batch Cancellation Fee plus (i) any Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion of any Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

14.3.3 The Customer may terminate a PSA at any time for convenience by giving not less than [***] [***] written notice to Fujifilm in which case clause 14.4 shall apply.

14.3.4 For clarity, if Customer cancels R&D Services which facilitate Commercial Manufacturing Services (for example technical transfer of the Process or Process Performance Qualification), Customer will be deemed to have also cancelled such Commercial Manufacturing Services for convenience.

14.4 Consequences of Termination of the Commercial Manufacturing Services

14.4.1 If Fujifilm terminates this Agreement under clause 14.2 or the PSA for Commercial Manufacturing Services under clause 14.6 or if the Customer terminates a PSA under clause 14.3.3, Customer shall pay the greater of:

(a) if there was more than [***] [***] remaining on that term: the unpaid Charges for the Minimum Annual Quantity for each Production Year during the Initial Term or Subsequent Term in which the termination took place;

(b) if there was less than [***] [***] remaining on that term: the unpaid Charges for the Minimum Annual Quantity for each Production Year during the Initial Term or Subsequent Term in which the termination took place plus the unpaid Charges for the Minimum Annual Quantity for each Production Year during the following Subsequent Term in aggregate capped at a total duration of [***]; and

(c) the amount of the binding Orders placed over (i) the preceding [***] or (ii) the period of time that the Customer has been placing Orders under this Agreement if less than [***];

PLUS, in each case, unpaid Ancillary Charges for Ancillary Services that have been performed, and (ii) such portion of any Ancillary Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

14.5 Termination of the Program Due to Technical Issues.

14.5.1 With respect to a Program, Fujifilm may terminate a Program at any time up to commencement of the manufacturing stages for such Program by giving written notice to the Customer if Fujifilm reasonably believes that it will be unable to carry out and complete the Program in accordance with the Scope of Work(s) or PSA(s) (as applicable) due to discovery of a factor (other than an breach by Fujifilm of clause 4.1) which:

(a) adversely affects the development of the Process; or

(a) adversely affects, or is likely to adversely affect, production of Product in the Facility when conducted in accordance with Fujifilm's standard operating procedures or methods; or

(b) is likely to have an adverse effect on a customer's Product license (being the license authorizing marketing of a medicinal product granted by a Regulatory Authority (also known as a "Marketing Authorisation" in [***])) or Manufacturing License (being the license to manufacture biotechnology-derived Drug Substances issued to Fujifilm by the applicable Regulatory Authority) as a result of the Product being introduced into the Facility and that customer was a customer of Fujifilm prior to the Program commencement,

provided that, in each case, the factor was not known and could not reasonably have been known at the commencement of the Program and provided further that Fujifilm has used Commercially Reasonable Efforts in its attempts to address the factor prior to such termination.

14.5.2 If Fujifilm terminates a Program under clause 14.5.1 then the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed and [***] of the Program Cancellation Fee plus (i) any Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion of any Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

14.6 Termination of a Scope of Work or PSA for material breach

14.6.1 If any party commits a material breach of a Scope of Work or PSA, the non-breaching party may give written notice to the other party, specifying the nature of the material breach and, if such material breach is not remedied within a reasonable period after receipt of such notice (provided, however, that the cure period shall be suspended during any time that a party seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to clause 16), then the non-breaching party shall have the right, in its sole discretion, to immediately terminate that Scope of Work or PSA (as applicable).

14.6.2 If Fujifilm terminates a Scope of Work or PSA under this clause 14.6 or all Scopes of Work or PSAs under clause 14.2 then, without prejudice to Fujifilm's other rights and remedies, the Program Cancellation Fee shall be payable by the Customer to Fujifilm plus (i) any Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion of any Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

14.7 If a party exercises any of its rights of termination in respect of only one or more SoWs or PSAs then:

14.7.1 this Agreement shall terminate in respect of those SoWs or PSAs (as applicable) and the provisions of this Agreement relating to termination of this Agreement shall apply in relation to those SoWs or PSAs (as applicable); and

14.7.2 in all other respects this Agreement shall continue in full force and those SoWs or PSAs (as applicable) in respect of which the party has terminated this Agreement will be deemed to be removed from the definition of the SoWs or PSAs (as applicable).

14.8 Additional Consequences of Termination

14.8.1 The termination of this Agreement, any PSA or any Scope of Work shall be without prejudice to the rights and remedies of any party which may have accrued up to the date of termination.

14.8.2 On termination of this Agreement, any PSA or any SoW (as applicable) for any reason whatsoever:

(a) save as set out in clause 9.14 the relationship of the parties shall cease and any rights or licenses granted under or pursuant to this Agreement shall cease to have effect save as (and to the extent) expressly provided for in this clause 14;

(a) the provisions of the following clauses together with any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect clauses 1, 8, 9, 9.14, 10, 11, 12, 14, 16, 18, and 23; and

(b) the Customer shall immediately pay to Fujifilm all of Fujifilm's outstanding unpaid invoices and interest and, in respect of Fujifilm Services and Ancillary Services supplied but for which no invoice has been submitted, Fujifilm may submit an invoice, which shall be payable immediately on receipt.

15. **FORCE MAJEURE**

15.1 Subject to clause 15.2, no party shall be liable to the other(s) in respect of, and neither party will be entitled to any remedy from any party affected by the Force Majeure Event for, any delay or non-performance of such affected party's obligations under any Scope of Work or PSA (except for the payment of money) arising from a Force Majeure Event.

15.2 If a party is delayed or prevented from performing its obligations due to a Force Majeure Event such party shall:

15.2.1 give notice of such delay or prevention due to the Force Majeure Event to the non-affected parties as soon as reasonably practical stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

15.2.2 use reasonable endeavors to mitigate the effects of such Force Majeure Event, provided that such party shall not be required to procure materials or services at unreasonable prices or under unreasonable terms; and

15.2.3 resume performance of its obligations as soon as reasonably practicable.

15.3 If a party's delay or prevention caused by the Force Majeure Event in question continues for more than [***] any party to the affected Scope of Work or PSA (as applicable) may give notice in writing to the other(s) to terminate that Scope of Work or PSA (as applicable). The notice to terminate must specify the termination date, which must not be less than [***] after the date on which the notice is given, and once such notice has been validly given, that Scope of Work or PSA (as applicable) will terminate on that termination date.

16. **DISPUTE RESOLUTION**

16.1 **Quality Disputes:** If there is a dispute in relation to or in connection with the QA Documents, such dispute shall be dealt with in accordance with the procedures set out in the Quality Agreement.

16.2 **Business Escalation:**

16.2.1 In respect of any dispute concerning this Agreement (other than a dispute in connection with the QA Documents) the parties shall seek to resolve the matter as follows:

(a) by referral in writing summarizing the nature of the dispute by a party in the first instance to the decision of each party's Program Manager;

(b) if the dispute is not resolved within [***] of its referral to the Program Managers it shall be referred to the decision of Fujifilm's Site Head and the Customer's [SVP Biologics Operations]; and

(c) if the dispute is not resolved within [***] of its referral to Fujifilm's Site Head and the Customer's SVP Biologics Operations it shall be referred to the decision of each party's President or Chief Executive Officer (as applicable/appropriate).

16.3 **Arbitration:** Any dispute, claim or controversy arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof (including all issues or disputes regarding the existence, validity, scope or applicability of this agreement to arbitrate, the arbitrability of any claims, and the proper parties to the arbitration) shall be determined by confidential arbitration in New York under JAMS International Arbitration Rules before three arbitrators. Judgment on the award may be entered in any court having jurisdiction.

16.4 **General:** Notwithstanding the provisions of this clause 16 any party may commence or take proceedings or seek remedies before the courts or any other competent authority for interim, interlocutory or injunctive remedies in relation to this Agreement.

17. **AUDIT**

17.1 Quality Audit:

17.1.1 The Customer may carry out quality audits at the times, and in accordance with the terms, set out in the Quality Agreement provided that access by the Customer and/or its representatives to records, information and systems shall be on a supervised basis, subject to the Customer complying with the security and confidentiality requirements of Fujifilm to protect information which relates to anything other than a Program and shall be limited to a maximum of two people for [***] [***] per annum.

17.1.2 Audit access shall not be extended to Fujifilm's confidential records, including details of financial transactions and contracts with third parties that relate to this Agreement.

17.1.3 If Fujifilm is in material breach of clause 4.1.3 of this Agreement or if the Customer reasonably believes that Fujifilm is in material breach of clause 4.1.3 of this Agreement, the Customer may upon giving reasonable written notice to Fujifilm carry out an audit on the same basis as in clauses 17.1.1 and 17.1.2.

17.1.4 Additional audits (other than those carried out pursuant to clause 17.1.3) may be carried out on the same basis as in clauses 17.1.1 and 17.1.2 subject to (i) payment of Fujifilm's costs and expenses and the agreement of a commercial rate; and (ii) the Customer ensuring such audit will not delay or disrupt Fujifilm's operations at the Facility.

17.2 Financial evidence and assistance:

17.2.1 Together with each invoice issued by Fujifilm to the Customer hereunder, Fujifilm shall provide reasonably detailed documentation to validate the amounts included on each invoice which are subject to the true-up mechanism contemplated in Schedule 1. The Customer may request reasonable additional validating information provided that (i) the Customer shall not request evidence validating a given amount more than once and (ii) it is acknowledged that Fujifilm may not provide copies of vendor invoices because Fujifilm may be prevented from doing so by law (including by vendor confidentiality obligations) and/or those invoices may not accurately represent the amounts invoiced to the Customer because of Fujifilm's use of SAP weighted average "actual cost".

17.2.2 Fujifilm will provide reasonable support to the Customer in the event that the Customer is audited by a third party and requires information to demonstrate proper payment of Fujifilm invoices under a SoW or PSA (as applicable).

18. **NOTICES**

18.1 Subject to clause 18.2 the parties may communicate with each other in any way that is normal in the course of their business.

18.2 Any notice given under clauses 3, 8, 9, 11, 12, 14, 15, 16, 17, 18.2, 19, 20 or 21 shall only be effective if it is in writing, sent to a party at its address or email address and for the attention of the individual, as set out in Schedule 3 (or such other address, email address or individual as that party may notify the other in accordance with this clause 18) and is given in accordance with clauses 18.2 to 18.4 below.

18.3 Notice may be given by hand or sent by email, recorded delivery, registered post or airmail and will be deemed to have been duly served:

18.3.1 if delivered by hand, at the time and date of delivery;

18.3.2 if sent by email, at the time and date of sending;

18.3.3 if sent by recorded delivery or registered post, [***] ([***]) [***] from the date of posting (such date as evidenced by postal receipt); and

18.3.4 if sent by registered airmail, five days from the date of posting,

provided that, where in the case of delivery by hand or transmission by email, such delivery or transmission occurs either after 4.00pm on a Business Day, or on a day other than a Business Day, service will be deemed to occur at 9.00am on the next Business Day.

18.4 In proving service of a notice it will be sufficient to prove that delivery was made or that the envelope containing the notice or document was properly addressed and posted (either by prepaid first class recorded delivery post or by prepaid airmail, as the case may be) or that no failed delivery message was received, as the case may be.

19. **EXPORT/IMPORT CONTROLS AND SANCTIONS COMPLIANCE**

19.1 The Customer shall at all times during the term of this Agreement comply with applicable Sanctions or Export/Import Laws and ensure that it has in place appropriate controls and safeguards to prevent any action being taken by it that would amount to or result in a violation of or non-compliance with any Sanctions or Export/Import Laws.

19.2 The Customer shall provide all information that Fujifilm may reasonably require from time to time in order for Fujifilm to assess and/or manage its compliance with Sanctions and Export/Import Laws (including provision of end-user statements or applicable Authorizations and notifying Fujifilm of any restrictions or export compliance obligations prior to providing Fujifilm access to controlled information/technology).

19.3 The Customer will not directly or indirectly use, sell, dispose of, (re)export, transship or otherwise transfer any Product, software, technology or Confidential Information: (i) unlawfully to any country in respect of which a Sanctions Authority maintains Sanctions or a Sanctioned Person; (ii) in a manner that would expose Fujifilm to the risk of negative consequences under Sanctions; or (iii) in violation of Export/Import Laws.

19.4 If any Authorization is required so that the performance of a Program does not contravene any Sanctions or Export/Import Laws, the Customer will at its own cost and expense obtain that Authorization and Fujifilm shall provide any commercially reasonable assistance (including reasonable information) that the Customer may require for the purposes of obtaining that Authorization. The Customer's rights and Fujifilm's obligations under this Agreement, any SoW or a PSA in relation to a Program shall immediately be suspended if any required Authorization is not obtained. In the event that the Customer's rights and Fujifilm's obligations are suspended for more than [***], a Program may be terminated immediately by Fujifilm giving written notice to the Customer. If Fujifilm terminates a Program under this clause 19.4 then the Customer shall pay the Charges that are due for the Fujifilm Services that have been performed during the Program and [***]% of the Program Cancellation Fee plus (i) any Charges owed in respect of Ancillary Services that have been performed, and (ii) such portion of any Charges that relate to any element of an unperformed Ancillary Service for which Fujifilm has already incurred or has committed to later incur under a non-cancellable order, unrecoverable costs and expenses.

19.5 The Customer shall Indemnify Fujifilm against any and all Liabilities which Fujifilm incurs as a result of the Customer's non-compliance with the terms of this clause 19.

19.6 In this clause 19 the following terms have the following meanings:

"Authorization"	all consents, licenses, authorisations, approvals, permissions, registrations, certificates and clearances and any precondition in any relevant jurisdiction;
"Export/Import Laws"	(a) any laws of the United States of America, the United Kingdom, the European Union or of any of its Member States or Japan that relate to the control of (re)export, transfer or import of Products, software or technology and technical data; or (b) any other (re)export, transfer or import controls or restrictions imposed or adopted by any government, state or regulatory authority in a country in which obligations under this Agreement are to be performed;

“Sanctions”	any economic, financial, trade or other sanction, embargo, import or export ban, prohibition on transfer of funds or assets or on performing services or equivalent measure imposed by any Sanctions Authority or by the laws of any state or any union of states from time to time;
“Sanctions Authority”	means (a) the Security Council of the United Nations, (b) the Organization for Security and Co-operation in Europe (c) the United Kingdom, (d) the European Union, (e) any Member State of the European Union, (f) the United States of America, (g) Japan (h) the governments and official institutions or agencies of any of paragraphs (a) to (h) above and (i) any other regulatory body imposing or enforcing sanctions legislation in any country or territory from which or into which the Customer is exporting or importing; and
“Sanctioned Person”	any person who appears on or is owned, operated or controlled by any person who appears on any list issued or maintained by any Sanctions Authority or is referred to in any list or public announcement issued by any Sanctions Authority, in each case as amended, supplemented or substituted from time to time.

20. **MODERN SLAVERY AND CORRUPTION**

20.1 Each party shall endeavour to hold itself and its suppliers to the highest performance, ethical and compliance standards, including basic human rights, not engaging in any activity, practice or conduct which would constitute an offence under anti-slavery legislation in the United Kingdom, the U.S.A or Denmark, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, each party acknowledges the value and importance of performance and ethical behaviour in its performance under this Agreement.

20.2 Each party warrants that on the Effective Date, each SoW Effective Date and each PSA Effective Date, it, its directors, officers or employees have not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advantage of any kind (or implied that they will or might do any such thing at any time in the future) in any way connected with this Agreement, a SoW or a PSA and that it has taken reasonable measures to prevent subcontractors, agents or other third parties, subject to its control or determining influence, from doing so.

20.3 The parties agree that, at all times in connection with and throughout the term of this Agreement, they will comply with and that they will take reasonable measures to ensure that their subcontractors, agents or other third parties will comply with all applicable anti-corruption legislation including the Bribery Act 2010, the Foreign Corrupt Practices Act 1977.

20.4 Each party shall not do, or omit to do, any act that would cause one of the other parties to be in breach of any anti-corruption legislation including the Bribery Act 2010, the Foreign Corrupt Practices Act 1977.

21. **ASSIGNMENT AND SUB-CONTRACTING**

21.1 Either party may assign or transfer all of its rights and responsibilities under this Agreement to:

21.1.1 an Affiliate, provided that such Affiliate has reasonable financial creditworthiness; or

21.1.2 a purchaser of all or substantially all of the equity of the assigning party provided that such third party has reasonable financial creditworthiness and, in the case of assignment by Customer, is not a Competitor; or

21.1.3 a purchaser of all or substantially all of assets to which this Agreement relates provided that such third party has reasonable financial creditworthiness and, in the case of assignment by Customer, is not a Competitor; or

21.1.4 an exclusive licensee of the Product provided that (i) provided that such third party has reasonable financial creditworthiness in the case of assignment by Customer, is not a Competitor and (ii) that the Customer no longer requires services from Fujifilm under this Agreement,

but not otherwise without written consent of the other party (such consent not to be unreasonably withheld or delayed) and provided that (a) the assignee agrees in writing to assume all obligations undertaken by its assignor in this Agreement and (b) in relation to assignment in part no such assignment shall relieve the assigning party of responsibility for the performance of any of its obligations under this Agreement.

21.2 If a party assigns or transfers all or any of its rights and responsibilities under clause 21.1 it shall immediately notify the other parties in writing.

21.3 Fujifilm may sub-contract all or any of its obligations under this Agreement provided that in relation to any subcontract manufacture, processing or handling of Product, Fujifilm will obtain the Customer's written consent (which may be by signature of the relevant SoW(s) or PSA(s) which specify that an obligation will be sub-contracted). Notwithstanding the foregoing, Fujifilm may utilize on-site third party personnel, such as temporary employees, contractors and consultants, to perform Fujifilm Services without obtaining the prior consent of the Customer.

21.4 The appointment of any subcontractor shall not relieve the party sub-contracting from any liability or obligation under this Agreement and the party sub-contracting shall be responsible for all acts and omissions of the subcontractor to the same extent as if they were its own acts or omissions.

22. **GENERAL**

22.1 Entire agreement: This Agreement and the Historic Documents contain all the terms which the parties have agreed with respect to their subject matter and supersede all previous agreements and understandings between the parties (whether oral or in writing) relating to such subject matter. Each party acknowledges and agrees that it has not been induced to enter into this Agreement by a statement or promise which it does not contain. Each party confirms that save as otherwise expressly set out in this Agreement and the Historic Documents, the other party gives no warranties either in this Agreement or elsewhere in connection with the provision of each Program. Nothing in this clause 22.1 shall exclude or limit a party's liability for fraud, including fraudulent misrepresentation.

22.2 Third party rights: Save as expressly set out in this Agreement, the parties do not intend that any person who is not a party to this Agreement shall have any right to enjoy the benefit or enforce any of the terms of this Agreement.

22.3 Variations: With the exception of Changes, which shall be subject to clause 13, no variation of this Agreement shall be valid unless in writing and signed by a duly authorized representative of each of the parties. A party is entitled assume that a representative of another party is authorized to act on that party's behalf if that individual is apparently or seemingly acting in the normal course of the business relationship. An exchange of emails shall not be capable of constituting an agreement to vary this Agreement.

22.4 Waiver: No failure or delay by a party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. The single or partial exercise by any party of any right, power or remedy under this Agreement shall not in any circumstances preclude any other or further exercise of it, or the exercise of any right, power or remedy. A waiver by any party of a breach of any provision of this Agreement shall not be considered as a waiver of a subsequent breach of the same or any other provision of this Agreement.

22.5 Severability: If any provision of this Agreement, a SoW or a PSA is found by any court or administrative body of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction then it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible that provision shall be deemed to be omitted from this Agreement, the SoW or the PSA (as applicable) in so far as this Agreement, that SoW or that PSA relates to that jurisdiction and the validity and enforceability of that provision in other jurisdictions and the other provisions of this Agreement, SoW or PSA shall not be affected or impaired.

22.6 Counterparts:

22.6.1 This Agreement may be executed in any number of counterparts. Any party may enter into this Agreement by executing a counterpart and all the counterparts taken together will constitute one and the same agreement. This Agreement shall not be effective until each party has signed one counterpart.

22.6.2 Transmission of an executed counterpart of this Agreement (but for the avoidance of doubt not just a signature page) by email (in PDF, JPEG or other agreed format) shall take effect as delivery of an executed counterpart of this Agreement. If this method of delivery is adopted, without prejudice to the validity of the Agreement so made, each party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter.

22.7 Publicity: The parties anticipate that there may be opportunities for joint or independent press releases or other announcements relating to the activities contemplated hereby. Notwithstanding the foregoing, no party shall use the name of the other party(ies) or the names of the employees of the other party(ies) nor disclose the terms of this Agreement, any SoW or any PSA in any press releases, advertising, or sales promotional material or in any publication without prior written permission of such party(ies). Such consent shall not be unreasonably withheld. This provision shall not restrict a party's ability to use the other parties names and to disclose the terms of this Agreement, any SoW or any PSA to the extent, in the reasonable opinion of such party's legal counsel, required by law or by the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such party has its securities listed or traded. In the event that such disclosure is required as aforesaid, the disclosing party shall make reasonable efforts to provide the other parties with advance notice and to coordinate reasonably with the other parties with respect to the wording and timing of any such disclosure, subject to the requirements of such securities laws.

23. **GOVERNING LAW**

23.1 The formation, existence, construction, performance, validity and all aspects whatsoever of this Agreement or any term of it and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature) shall be governed by, and construed in accordance with the State Law of Delaware, and subject to clause 16 the parties irrevocably submit to the jurisdiction of the courts of Delaware.

IN WITNESS of the above the parties have signed this Agreement on the dates set out next to their signature.

Schedule 1 Charges

The calculation of Charges for Fujifilm Services differs whether the Fujifilm Services are R&D Services (details of which are contained in Part 1 of this Schedule 1) or Commercial Manufacturing Services (details of which are contained in Part 2 of this Schedule 1).

PART 1 OF SCHEDULE 1– CHARGES IN RESPECT OF R&D SERVICES

The Customer will pay to Fujifilm the Charges for the R&D Services in accordance with the Scope of Work and clause 8 (the R&D Services being the services to be performed by Fujifilm that are described in the relevant Scope of Work that are not Ancillary Services).

The Customer will also pay Ancillary Charges to Fujifilm in consideration of the research and development and technical consultancy services in relation to the procurement, testing and management of Consumables; Subcontracted Work (including delivery of material to and from such subcontractors); Process-Specific Equipment (including installation, qualification and maintenance thereof); Modifications; Special Waste; and delivery to Fujifilm's subcontractors and to the Customer (including packaging, insurance, export clearance and transport of Materials) (the "**Ancillary Services**") as calculated in accordance with this Schedule 1.

1. **Charges for Consumables in Non-Manufacturing Stage and Manufacturing Stage**

1.1 At the time set out in the Scope of Work, or in the course of a Program as mutually agreed in writing by the parties, the Customer shall pay to Fujifilm an amount in advance in consideration of the Ancillary Services relating to the purchase of Consumables intended to be used during the applicable Non-Manufacturing Stages and manufacturing stages. This will be an amount based upon an estimation of the sums required to purchase Consumables based upon Fujifilm's historical data from previous manufactures at the applicable scale of production plus [***] of such sums (the "**Consumables Advance Payment**").

1.2 On completion of each applicable Non-Manufacturing Stage or manufacturing stage, Fujifilm shall calculate the expenditure incurred in respect of Consumables procured for use during such Non-Manufacturing Stage or manufacturing stage and shall add a sum equivalent to [***] of all such expenditure on to such sum, the aggregate amount being referred to as "**Actual Production Expenditure**".

1.3 If the Actual Production Expenditure is greater than the Consumables Advance Payment plus any other amounts paid under paragraph 1.4, Fujifilm shall issue a further invoice for the Ancillary Services in relation to the Consumables for a sum equivalent to the difference on a [***] basis. If the Actual Production Expenditure is less than the Consumables Advance Payment, upon reconciliation, Fujifilm shall issue a credit note against the earlier invoice for a sum equivalent to the difference to be applied to the Charges for the following Stage (if there is one).

1.4 Each [***], Fujifilm may issue an invoice to the Customer in relation to the Ancillary Services regarding any Consumables used during or procured for use in any Stage during the previous [***] (or if longer, since the last invoice under this paragraph 1.4 was issued) in amounts which are not covered by the Consumables Advance Payment equivalent to the expenditure on such additional Consumables during the previous [***] plus an amount equal to [***] of such expenditure.

2. **Additional Charges in Respect of Subcontracted Work, Process-Specific Equipment, Modifications, Special Waste and delivery of Materials**

2.1 Fujifilm shall invoice the Customer for the Ancillary Services relating to the Subcontracted Work, Process-Specific Equipment, Modifications, disposal of Special Waste and delivery of Materials as the case may be in the same amount as the expenditure which Fujifilm incurs in respect of such Ancillary Services plus a sum equivalent to [***] of such expenditure.

2.2 Fujifilm shall issue invoices for such Ancillary Services either at the time Fujifilm incurs expenditure in respect of the Subcontracted Work, Process-Specific Equipment, Modifications, disposal of Special Waste and/or delivery of Materials or as set out in the relevant SoW as the case may be.

3. **Purchase of Process-Specific Consumables and Process-Specific Equipment by the Customer on completion of the relevant Stage or termination**

3.1 Subject to:

3.1.1 clause 10.3;

3.1.2 the manufacturer's consent and requirements (if applicable) and subject to the Customer's warranty that it will purchase a direct license of any relevant firmware/software required to operate the Process-Specific Equipment;

3.1.3 and the payment of all relevant Charges,

the Customer shall have an option to purchase from Fujifilm such Process-Specific Equipment and/or Process-Specific Consumables purchased by Fujifilm under paragraphs 1 and 2 of this Schedule 1 as remain following completion of the relevant Stage for which such Process-Specific Equipment and/or Process-Specific Consumables were purchased for consideration of [***] payable, if the work is performed in the USA respectively, at the time of such sale.

3.2 The option in paragraph 3.1 shall be exercised within [***] following completion of the relevant Stage under which such Process-Specific Equipment and/or Process-Specific Consumables were purchased or termination of this Agreement, (whichever occurs first).

3.3 The Customer shall be responsible for any cost and expense associated with removal/delivery of such Process-Specific Equipment and/or Process-Specific Consumables and documenting such sale. Such Process-Specific Equipment and/or Process-Specific Consumables shall be delivered Ex Works the Facility (Incoterms 2020). Risk in and title to such Process-Specific Equipment and/or Process-Specific Consumables shall pass on delivery.

3.4 Fujifilm shall be free to use or destroy (at the Customer's cost) any item(s) of Process-Specific Equipment or Process-Specific Consumables in respect of which the option referred to in this paragraph 3 is not exercised or for which their assigned expiry date has passed.

4. **Product Samples, Cell Banks and other materials on completion or termination**

4.1 Prior to completion of the R&D Services element of a Program, the Customer shall notify Fujifilm what (if any) samples and/or cell banks used during the Program the Customer wishes Fujifilm to deliver to the Customer and, subject to clause 10.3, delivery of those samples/cell banks shall (a) be subject to payment of all Charges for such Program and (b) take place in accordance with clause 7. If the Customer does not give any such notification to Fujifilm prior to completion of the R&D Services element of a Program, Fujifilm may destroy such samples and/or cell banks without further notice at the Customer's cost.

4.2 Fujifilm shall be required to return or destroy, in a manner of its choosing and without further notice to the Customer, any Product, samples, cell banks or other property of the Customer which remains in the possession of Fujifilm in excess of [***] ([***]) [***] following the effective date of termination.

5. **Batch Cancellation Fees**

Batch Cancellation Fees are only applicable to R&D Services (Batches delivered or to be delivered as part of the Commercial Manufacturing Services are not cancellable and must be paid in full).

Period prior to Commencement of Stage	Percentage of Batch Fee
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

*For clarity, this will include manufacturing stages that have commenced

PART 2 OF SCHEDULE 1– CHARGES IN RESPECT OF COMMERCIAL MANUFACTURING SERVICES

The Customer will pay to Fujifilm the Charges for the Commercial Manufacturing Services in accordance with the PSA and clause 8 (the Commercial Manufacturing Services being the services to be performed by Fujifilm that are described in the relevant PSA that are not Ancillary Services).

1. [***]

1.1 [***]

2. **Batch Fee**

2.1 The Batch Fee for the Product will be specified in the relevant PSA.

2.2 In respect of each Batch the Customer shall pay:

2.2.1 [***] of the Batch Fee no later than [***] prior to Batch production (vial thaw of the Batch);

2.2.2 [***] of the Batch Fee on initiation of pre-production activities relating to the Batch, which shall occur no earlier than [***] prior to vial thaw;

2.2.3 [***] of the Batch Fee on vial thaw; and

2.2.4 [***]of the Batch Fee upon delivery or deemed delivery in accordance with clause 7.2.

2.3 The Customer agrees that for every Production Year it will pay for the number of Batches in the Binding Forecast for that Production Year even if it Orders less Batches than the number of Batches provided for in the Binding Forecast for that Production Year and Fujifilm will invoice the Customer for any such shortfall in Batches at the Batch Fee at the end of each Production Year.

3. **Charges for Consumables and Sub-Contracted Work**

3.1 In addition to the Batch Fee for each Batch, the Customer will pay Fujifilm the Ancillary Charges for Consumables and Subcontracted Work (which for the purposes of the Commercial Manufacturing Services are the "**Ancillary Services**") at a rate of actual cost to Fujifilm plus [***]. The Ancillary Charges shall be payable when invoiced by Fujifilm in accordance with the provisions of paragraphs 2.3 and 3.4 below.

3.2 Fujifilm will estimate the Ancillary Charges per Batch in the PSA, based upon Fujifilm's historical data from previous manufactures at the applicable scale of production ("**Estimated Ancillary Charges**"). If the cost of Consumables and Subcontracted Work increases by more than [***] Fujifilm shall revise the Estimated Ancillary Charges and will notify the Customer of the same.

3.3 On or at any time after receipt of an Order Fujifilm may invoice to Customer an amount equal to [***] of the Estimated Ancillary Charges for Batches in that Order.

3.4 On completion of each Batch, Fujifilm shall calculate the actual Ancillary Charges (with Fujifilm's [***] margin added) in respect of such Batch and issue a further invoice for the Ancillary Services for a sum equivalent to the difference between the Estimated Ancillary Charges in respect of that Batch and the amount already invoiced under paragraph 3.3.

4. **Customer Deliverables and other materials on termination**

4.1 The PSA shall specify what Customer Deliverables are required.

4.2 Within [***] ([***]) [***] of termination of this Agreement, the Customer shall notify Fujifilm what (if any) Customer Deliverables the Customer wishes Fujifilm to deliver to the Customer and, subject to clause 10.3, delivery of those Customer Deliverables shall take place in accordance with clause 7. If the Customer does not give any such notification to Fujifilm within [***] of termination of this Agreement, Fujifilm may destroy such samples and/or cell banks without further notice at the Customer's cost.

4.3 Provided that the Customer has paid for any Materials in relation to which payment is due, Fujifilm shall deliver Materials to Customer in accordance with clause 7.

5. **Price Increases**

5.1 The Batch Fee and Annual Service Fee shall increase on [***] of each year during each of the Initial Term or Subsequent Term in an amount equal to the increase, if any, in the pharmaceutical preparation manufacturing index [***] (from [***] of the preceding year to [***] of the last year) since the PSA Effective Date or the last change in such price.

5.2 The Batch Fee shall not decrease.

5.3 Notwithstanding the foregoing, if Fujifilm documented operating expenses increase by [***]% or more the parties will negotiate an equitable increase to Batch Fee.

Schedule 2 FORECASTING AND ORDERS

1. **Application of Schedule 2**

1.1 This Schedule 2 applies only to PSAs for Commercial Manufacturing Services and Orders placed under such PSAs. Any reference to a PSA or an Order, shall be deemed to relate to PSAs or Orders for Commercial Manufacturing Services.

1.2 For the avoidance of doubt this Schedule 2 does not apply to Scopes of Work for R&D Services.

2. **Minimum Orders**

2.1 The Minimum Annual Quantity is the number of Batches that the Customer agrees to order and pay for during the applicable Production Year.

2.2 The Minimum Annual Quantity for each Production Year of the PSA's Initial Term will be set out in the applicable PSA.

2.3 The Maximum Annual Quantity is the maximum number of Batches that Fujifilm agrees it can manufacture for the Customer during the applicable Production Year.

2.4 The Maximum Annual Quantity for each Production Year of the PSA's Initial Term will be set out in the applicable PSA.

2.5 In each Subsequent Term of a PSA, the Minimum Annual Quantity and Maximum Annual Quantity for each Production Year during that Subsequent Term will be the same as for the Initial Term or previous Subsequent Term (as applicable) unless when the parties agree to extend the PSA the parties agree otherwise in writing in the Change in which such Subsequent Term has been agreed.

3. **Forecasting**

3.1 Starting on [***], Customer shall provide a rolling [***] Batch forecast on or before [***] [***] of each [***]. The first forecast shall be for relevant Batches (i.e., Batches ordered pursuant to a PSA) manufactured in [***]. The first [***] of each forecast shall be binding, in that Customer shall be obligated to pay for the Batches provided therein, regardless of circumstances. Customer may deviate between [***] and [***] of the forecasted number of Batches identified in the [***] [***]of each forecast. [***] of each forecast shall be for information and planning purposes only.

For each subsequent year, [***] of the previous year's forecast shall become [***], [***] shall become [***] (which shall become binding, and may only deviate between [***] and [***] of what was forecasted in the previous year), and [***] shall become [***] (since [***] is for information purposes only, it may be deviated from, but in no case shall it be greater than [***] Batches or less than [***] Batches), and a new [***] shall be provided, and so on.

Starting in the year [***], Customer shall order and pay for at least [***] Batches per year and Fujifilm shall be obligated to manufacture no more than [***] Batches each year. Should Customer request more than [***] Batches in a [***], Fujifilm may use reasonable efforts to manufacture those excess Batches but shall be under no obligation to do so.

For illustrative purposes only, the below chart lays out an example of how the rolling forecast may look:

	[***]	[***]	[***]	[***]
Percent Binding	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

The parties will agree in good faith to amend the forecasting requirements in this clause if Commercial Manufacturing Services cannot be provided by Fujifilm or if the Commercial Trigger is not achieved solely due to a reason within Fujifilm's reasonable control.

Ordering

3.2 The Customer will issue a written purchase order (the "**Order**") for the Batches to be delivered each Production Year to Customer under a PSA not less than [***] prior to commencement of the relevant Production Year.

3.3 Fujifilm shall acknowledge Orders in writing within [***] of receipt.

3.4 Once acknowledged by Fujifilm Orders are non-cancellable by either party.

3.5 Orders, Order acknowledgements and/or other similar documentation submitted by either party in conducting activities under this Agreement are for administration purposes only and (notwithstanding any statement or terms stated within such documentation) shall not add to or modify the terms of this Agreement.

Schedule 3 Addresses for Notice

Fujifilm:	**Copied to:**
Chief Executive Officer 23.2 FUJIFILM Diosynth Biotechnologies 23.3 Belasis Avenue 23.4 Billingham, TS23 1LH 23.5 England Email: [***]	General Counsel FUJIFILM Diosynth Biotechnologies Belasis Avenue Billingham, TS23 1LH England Email: [***]
Customer: Contact: Senior Vice President, Operations Address: 3020 Carrington Mill BLVD, Suite 475 Morrisville, NC 27560 Nominated email address: [***]	 Contact: Legal Counsel Address: 3020 Carrington Mill Blvd, Suite 475 Morrisville, NC 27560 Nominated email address: [***]

Schedule 4 – Attachments

[***]

PSA Template

This PSA is made subject to, and incorporates the terms of, the Master Services and Supply Agreement made between **FUJIFILM DIOSYNTH BIOTECHNOLOGIES NORTH CAROLINA, INC.** at 100 Biotechnology Avenue, Holly Springs, NC 27540 United States of America(" **Fujifilm**") and **TG Therapeutics, Inc.** incorporated and registered in [a Delaware corporation] with company whose registered office is at 3020 Carrington Mill Blvd, Suite 475, Morrisville, North Carolina 27560 (the "**Customer**") dated [INSERT DATE OF MSSA] (the " **Agreement**"). Defined terms used in this PSA shall have the meaning given to them in the Agreement unless the context otherwise requires or unless otherwise defined herein.

The parties have agreed the following in relation to the commercial manufacture of Product by Fujifilm in accordance with the Agreement:

Product:	[[INSERT]
Term of this PSA:	This PSA shall come into force on the PSA Effective Date and shall, unless terminated sooner by a party in accordance with the terms of the Agreement, continue for an initial period of [***] (the "**Initial Term**"). The term of this PSA shall renew automatically for a period of [***] (the " **Subsequent Term**") on expiry of: 23.5.1 the Initial Term; and 23.5.2 each Subsequent Term, unless and until terminated by either party giving no less than [***] prior written notice to the other, such notice to expire on the last day of the Initial Term or of any Subsequent Term.
Batch Price:	[INSERT]
Estimated Pass Through Costs (per Batch):	[INSERT]
Annual Service Fees	[INSERT]
Minimum Annual Quantity:	[INSERT]
Maximum Annual Quantity:	[INSERT]
Shelf Life (of Product)	[INSERT]
Program Manager:	[INSERT]
Customer Deliverables:	[INSERT]
Applicable Quality Agreement:	The Quality Agreement signed by the parties on [INSERT DATE] [*and having document reference number [INSERT]*.

This PSA is hereby agreed between the parties.

SIGNED for and on behalf of **FUJIFILM DIOSYNTH BIOTECHNOLOGIES NORTH CAROLINA, INC. :**

Signature:

Title:

Date:

SIGNED for and on behalf of **TG THERAPEUTICS, INC**:

Signature:	**Signature:**
Title:	**Title:**
Date:	**Date:**

Agreement Signature Page

SIGNED for and on behalf of FUJIFILM DIOSYNTH NORTH CAROLINA, INC.:

Signature:

Title:

Date:

SIGNED for and on behalf of FUJIFILM DIOSYNTH DENMARK APS:

Signature:

Title:

Date:

SIGNED for and on behalf of **TG THERAPEUTICS, INC.**:

Signature:

Title:

Date:

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 7, 2024

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

Exhibit 31.2

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

I, Sean A. Power, certify that:

1. I have reviewed this 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 7, 2024

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

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF

TG THERAPEUTICS, INC.

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 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 7, 2024

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

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF

TG THERAPEUTICS, INC.

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 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 7, 2024

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