REFINITIV

DELTA REPORT

10-Q

TGTX - TG THERAPEUTICS, INC.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	4650
CHANGES	156
DELETIONS	3912
ADDITIONS	582

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM10-Q

☐ QUARTERLY REPORT PURSUANT TO SECTION13 OR 15(d)OF THE

SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2023 September 30, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION13 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
Delaware(State or other jurisdiction of incorporation or organization)	**36-3898269**(I.R.S. Employer Identification No.)
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3020 Carrington Mill Blvd, Suite 475
Morrisville, North Carolina27560
(Address including zip code of principal executive offices)

(212)

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

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock, par value $0.001	TGTX	TGTX Nasdaq Capital Market 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 150,977,564151,410,073 shares of the registrant's common stock, $0.001 par value, outstanding as of August 2, 2023 November 1, 2023.

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TG THERAPEUTICS,INC.

FORM10-Q

FOR THE QUARTER ENDED June 30, 2023 September 30, 2023

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- **our ability to obtain and maintain regulatory approvals for our product candidates, including TG-1701 and TG-1801, as well as any other p**
- **our ability to adapt and expand our commercial infrastructure to successfully launch, market and sell BRIUMVI and our other product c**
- **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**
- **the initiation, timing, progress and results of our pre-clinical 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**
- **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 candida**
- **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 o**
- **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; and**
- **developments relating to our competitors and our industry.**

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SUMMARY RISK FACTORS

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

Risks Related to Commercialization

- 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 TG-1701 and TG-1801 in B-cell disorders.
- We have limited experience operating as a commercial company, and, as a result, the marketing and sale of BRIUMVI in 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 communit
- If the market opportunities for BRIUMVI and any future products for which we may receive approval, including TG-1701 or TG-1801 in B-cell disorders, are smaller th 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 cc 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 obtain or maintain regulatory approval for our product or product candidates and ultimately cannot commercialize one or more of them, 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 prof
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorab 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 u

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 compliance 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 civil or criminal 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 approv

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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 n 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

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 unfavo
- 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

- We have incurred significant operating losses since our inception and anticipate that we will continue to may incur losses for in the foreseeable future.
- We While we don't expect to need to raise additional capital, we may need to raise substantial additional funding. do so. If we are unable to raise capital, if needed, we m 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

- Public health issues including an epidemic or global pandemic, and specifically the pandemic caused by COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.
- Patients and healthcare providers have raised concerns that immunosuppressive products, like anti-CD20 antibodies and other B-cell targeted agents, may increase 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 a
- 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 migh
- 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 derivati
- Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data could harm our business and subject u

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

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PARTI. FINANCIAL INFORMATION

ITEM1. FINANCIAL STATEMENTS

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

	June 30, 2023 (Unaudited)	December 31, 2022 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 97,009	$ 102,304
Short-term investment securities	47,896	59,374
Accounts receivable, net	17,484	—
Inventories	30,234	—
Prepaid research and development	4,863	4,237
Other current assets	11,088	2,359
Total current assets	208,574	168,274
Restricted cash	1,279	1,273
Long-term investment securities	—	12,404
Right of use assets	8,475	8,888
Leasehold interest, net	1,521	1,627
Equipment, net	206	307
Goodwill	799	799
Total assets	$ 220,854	$ 193,572
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 62,945	$ 42,019
Other current liabilities	1,569	1,169
Lease liability – current portion	1,512	1,581
Accrued compensation	6,641	8,432
Total current liabilities	72,667	53,201
Deferred revenue, net of current portion	229	305
Loan payable – non-current	97,700	71,135
Lease liability – non-current	9,805	10,344
Total liabilities	180,401	134,985
Commitments and contingencies		

Stockholders' equity:		
Common stock, $0.001 par value per share (175,000,000 shares authorized, 150,969,323 and 146,426,697 shares issued, 150,928,014 and 146,385,388 shares outstanding at June 30, 2023 and December 31, 2022, respectively)	151	146
Additional paid-in capital	1,654,411	1,585,708
Treasury stock, at cost, 41,309 shares at June 30, 2023 and December 31, 2022	(234)	(234)
Accumulated deficit	(1,613,875)	(1,527,033)
Total stockholders' equity	40,453	58,587
Total liabilities and stockholders' equity	$ 220,854	$ 193,572

	September 30, 2023 (Unaudited)	December 31, 2022 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 150,902	$ 102,304
Short-term investment securities	78,257	59,374
Accounts receivable, net	39,320	—
Inventories	33,553	—
Prepaid research and development	5,001	4,237
Other current assets	12,081	2,359
Total current assets	319,114	168,274
Restricted cash	1,282	1,273
Long-term investment securities	—	12,404
Right of use assets	8,271	8,888
Leasehold interest, net	1,468	1,627
Equipment, net	133	307
Goodwill	799	799
Total assets	$ 331,067	$ 193,572
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 39,741	$ 42,019
Other current liabilities	1,217	1,017
Lease liability – current portion	1,479	1,581
Deferred revenue - current portion	6,903	152
Accrued compensation	8,338	8,432
Total current liabilities	57,678	53,201
Deferred revenue, non-current portion	190	305
Loan payable – non-current	98,908	71,135
Lease liability – non-current	9,522	10,344
Total liabilities	166,298	134,985
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value per share (175,000,000 shares authorized, 151,490,731 and 146,426,697 shares issued, 151,449,422 and 146,385,388 shares outstanding at September 30, 2023 and December 31, 2022, respectively)	151	146
Additional paid-in capital	1,664,797	1,585,708
Treasury stock, at cost, 41,309 shares at September 30, 2023 and December 31, 2022	(234)	(234)

Accumulated deficit	(1,499,945)	(1,527,033)
Total stockholders' equity	164,769	58,587
Total liabilities and stockholders' equity	$ 331,067	$ 193,572

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

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 16,036	$ 556	$ 23,801	$ 2,534
License revenue	38	38	76	76
Total revenue	$ 16,074	$ 594	$ 23,877	$ 2,610
Costs and expenses:				
Cost of product revenue	1,911	23	2,768	260
Research and development:				
Noncash compensation	5,664	2,328	7,247	4,223
Other research and development	22,458	24,546	36,744	70,693
Total research and development	28,122	26,874	43,991	74,916
Selling, general and administrative:				
Noncash compensation	6,877	(3,304)	12,117	(3,077)
Other selling, general and administrative	23,838	15,942	46,666	36,324
Total selling, general and administrative	30,715	12,638	58,783	33,247
Total costs and expenses	60,748	39,535	105,542	108,423
Operating loss	(44,674)	(38,941)	(81,665)	(105,813)
Other expense (income):				
Interest expense	3,627	3,017	6,471	5,681
Other income	(691)	(1,448)	(1,295)	(1,971)
Total other expense (income), net	2,936	1,569	5,176	3,710
Net loss	$ (47,610)	$ (40,510)	$ (86,841)	$ (109,523)
Basic and diluted net loss per common share	$ (0.34)	$ (0.30)	$ (0.62)	$ (0.81)
Weighted-average shares used in computing basic and diluted net loss per common share	141,503,738	134,779,904	140,911,295	134,591,250

	Three months ended September 30,	Nine months ended September 30,

	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 25,068	$ 56	$ 48,868	$ 2,591
License, milestone and other revenue	140,747	38	140,823	114
Total revenue	$ 165,815	$ 94	$ 189,691	$ 2,705
Costs and expenses:				
Cost of revenue	3,509	2	6,277	262
Research and development:				
Noncash compensation	2,915	3,249	10,162	7,471
Other research and development	11,838	17,552	48,581	88,246
Total research and development	14,753	20,801	58,743	95,717
Selling, general and administrative:				
Noncash compensation	6,269	3,740	18,386	663
Other selling, general and administrative	26,500	10,514	73,167	46,840
Total selling, general and administrative	32,769	14,254	91,553	47,503
Total costs and expenses	51,031	35,057	156,573	143,482
Operating income (loss)	114,784	(34,963)	33,118	(140,777)
Other expense (income):				
Interest expense	3,713	1,648	10,184	7,329
Other income	(2,859)	(793)	(4,154)	(2,765)
Total other expense (income), net	854	855	6,030	4,564
Net income (loss)	$ 113,930	$ (35,818)	$ 27,088	$ (145,341)
Net income (loss) per common share:				
Basic	$ 0.80	$ (0.26)	$ 0.19	$ (1.08)
Diluted	$ 0.73	$ (0.26)	$ 0.19	$ (1.08)
Weighted-average shares outstanding:				
Basic	142,871,227	135,327,035	141,571,785	134,839,207
Diluted	155,871,749	135,327,035	145,952,913	134,839,207

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

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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		Common Stock		Additional paid-in	Treasury Stock	
	Shares	Amount	capital	Shares	Amount	Deficit	Total	Shares	Amount	capital	Shares	Amount
Balance at January 1, 2022	143,292,043	$ 143	$1,565,942	41,309	$ (234)	$ (1,328,698)	$ 237,153	143,292,043	$ 143	$ 1,565,942	41,309	$ (234)
Issuance of common stock in connection with exercise of options	30,411	*	125	—	—	—	125	30,411	*	125	—	—
Issuance of restricted stock	1,852,626	2	(2)	—	—	—	—	1,852,626	2	(2)	—	—
Forfeiture of restricted stock	(591,746)	*	*	—	—	—	—	(591,746)	*	*	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	2,121	—	—	—	2,121	—	—	2,121	—	—
Net loss	—	—	—	—	—	(69,013)	(69,013)	—	—	—	—	—
Balance at March 31, 2022	144,583,334	145	1,568,186	41,309	(234)	(1,397,711)	170,386	144,583,334	145	1,568,186	41,309	(234)
Issuance of common stock in connection with exercise of options	33,044	*	135	—	—	—	135	33,044	*	135	—	—
Issuance of restricted stock	1,830,320	2	(2)	—	—	—	—	1,830,320	2	(2)	—	—
Forfeiture of restricted stock	(1,248,640)	(2)	1	—	—	—	(1)	(1,248,640)	(2)	1	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	(975)	—	—	—	(975)	—	—	(975)	—	—
Net loss	—	—	—	—	—	(40,510)	(40,510)	—	—	—	—	—
Balance at June 30, 2022	145,198,058	145	1,567,345	41,309	(234)	(1,438,221)	129,035	145,198,058	145	1,567,345	41,309	(234)
Issuance of common stock in connection with exercise of options								67,152	*	275	—	—
Issuance of restricted stock								368,660	1	—	—	—

Forfeiture of restricted stock	(234,726)	(1)	—	—	—	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	6,989	—	—	
Net loss	—	—	—	—	—	
Balance at September 30, 2022	145,399,144	145	1,574,609	41,309	(234)	

	Common Stock		Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2023	146,426,697	$ 146	$1,585,708	41,309	$ (234)	$ (1,527,033)	$ 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	1,593,783	41,309	(234)	(1,566,265)	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)	*		—	—	—	—

	Common Stock		Additional paid-in	Treasury Stock		Acc
	Shares	Amount	capital	Shares	Amount	
Balance at January 1, 2023	146,426,697	$ 146	$ 1,585,708	41,309	$ (234)	$
Issuance of common stock in connection with exercise of options	66,701	*	363	—	—	
Issuance of restricted stock	3,017,736	3	(3)	—	—	
Warrants issued with debt financing	—	—	595	—	—	
Forfeiture of restricted stock	(73,787)	*	—	—	—	
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	7,120	—	—	
Net loss	—	—	—	—	—	
Balance at March 31, 2023	149,437,347	149	1,593,783	41,309	(234)	
Issuance of common stock in connection with exercise of options	76,955	*	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					
Issuance of common stock in public offering (net of offering costs of $0.8 million)								1,385,700	2	46,295	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	13,582	—	—	—	13,582	—	—	13,582	—	—
Net loss	—	—	—	—	—	(47,610)	(47,610)	—	—	—	—	—
Balance at June 30, 2023	150,969,323	151	1,654,411	41,309	(234)	(1,613,875)	40,453	150,969,323	151	1,654,411	41,309	(234)
Issuance of common stock in connection with exercise of options								102,500	*	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	—	—
Net income (loss)								—	—	—	—	—
Balance at September 30, 2023								151,490,731	151	1,664,797	41,309	(234)

Amount less than one thousand dollars

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

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

	Six months ended June 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (86,841)	$(109,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	19,364	1,146
Depreciation and amortization	100	154
Amortization of premium (discount) on investment securities	(487)	(17)
Amortization of debt issuance costs	1,100	922
Amortization of leasehold interest	106	106
Noncash change in lease liability and right of use asset	990	1,014
Change in fair value of notes payable	261	(276)
Changes in assets and liabilities:		
Increase in inventory	(28,896)	—
(Increase) decrease in other current assets	(9,316)	8,054
(Increase) decrease in accounts receivable	(17,484)	1,301
Increase (decrease) in accounts payable and accrued expenses	19,136	(21,355)
Decrease in lease liabilities	(1,187)	(995)
Increase in other current liabilities	1,323	1,740
Decrease in deferred revenue	(76)	(76)
Net cash used in operating activities	(101,907)	(117,805)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of short-term securities	46,501	38,525
Investment in held-to-maturity securities	(22,168)	(71,810)
Purchases of PPE	—	(7)
Net cash provided by (used in) investing activities	24,333	(33,292)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of loan payable	—	(975)
Issuance of common stock, net	46,296	—
Proceeds from exercise of options	1,114	260
Proceeds from debt financings	25,000	—
Financing costs paid	(125)	—
Net cash provided by (used in) financing activities	72,285	(715)
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,289)	(151,812)

CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	103,577	300,151
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 98,288	$ 148,339
Reconciliation to amounts on condensed consolidated balance sheets:		
Cash and cash equivalents	$ 97,009	$ 147,073
Restricted cash	1,279	1,266
Total cash, cash equivalents and restricted cash	$ 98,288	$ 148,339
Cash paid for:		
Interest	$ 3,929	$ 2,622
NONCASH TRANSACTIONS		
Deferred financing costs	$ 1,238	$ —
Warrants issued with debt financing	$ 595	$ —

	Nine months ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 27,088	$ (145,341)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	28,548	8,134
Depreciation and amortization	173	230
Amortization of premium (discount) on investment securities	(704)	(172)
Amortization of debt issuance costs	1,739	1,383
Amortization of leasehold interest	159	159
Noncash change in lease liability and right of use asset	1,473	2,205
Change in fair value of notes payable	(71)	(241)
Changes in assets and liabilities:		
Increase in inventory	(31,432)	—
(Increase) decrease in other current assets	(10,365)	7,842
(Increase) decrease in accounts receivable	(39,320)	1,389
Decrease in accounts payable and accrued expenses	(2,372)	(27,436)
Decrease in lease liabilities	(1,780)	(1,741)
Increase in other current liabilities	2,024	1,403
Increase (decrease) in deferred revenue	6,637	(114)
Net cash used in operating activities	(18,203)	(152,300)

CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of short-term securities	72,551	67,005
Investment in held-to-maturity securities	(78,447)	(103,276)
Purchases of PPE	—	(11)
Net cash used in investing activities	(5,896)	(36,282)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of loan payable	—	(975)
Issuance of common stock, net	46,297	—
Proceeds from exercise of options	1,534	535
Proceeds from debt financings	25,000	—
Financing costs paid	(125)	—
Net cash provided by (used in) financing activities	72,706	(440)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	48,607	(189,022)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	103,577	300,151
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 152,184	$ 111,129
Reconciliation to amounts on condensed consolidated balance sheets:		
Cash and cash equivalents	$ 150,902	$ 109,860
Restricted cash	1,282	1,269
Total cash, cash equivalents and restricted cash	$ 152,184	$ 111,129
Cash paid for:		
Interest	$ 6,338	$ 3,908
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.

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TG Therapeutics,Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

Unless the context requires otherwise, references in this report to "TG," "TG," "Company," "Company," "we," "we," "us" "us" and "our" "our" refer to TG Therapeutics,Inc. and our subsidiaries.

NOTE1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

TG Therapeutics is a fully-integrated, commercial stage, biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has received approval from the United States Food and Drug Administration (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 has 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-Q10-Q and Article 10 of Regulation S-X 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-K10-K for the year ended December 31, 2022December 31, 2022. The accompanying condensed December 31, 2022December 31, 2022 balance sheet has been derived from these statements. The results of operations for the three and sixnine months ended June 30, 2023September 30, 2023 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

In December 2018, the Company created an Australian corporation, TG Therapeutics AUS Pty Ltd. (TG AUS), as a wholly-owned subsidiary. This corporation's functional currency, the Australian dollar, is also its reporting currency, and its financial statements are translated to U.S. dollars, the Company's reporting currency, prior to consolidation. The activities of TG AUS result in immaterial currency translation adjustments and, thus, are included in Other Income/Expense on the Company's condensed consolidated statement of operations. The accompanying condensed consolidated financial statements include the accounts of the Company and its subsidiaries, and all intercompany accounts and transactions have been eliminated in consolidation.

Liquidity and Capital Resources

We

Historically, we have incurred operating losses since our inception inception; however, the Company experienced a net profit during the three andnine months ended September 30, 2023 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 expect to continue to incur operating losses for in the foreseeable future near term and may never become profitable. As of June 30, 2023September 30, 2023, we have an accumulated deficit of $1.6$1.5 billion.

Our major sources of cash have been proceeds from private placement and public offering of equity securities, from our loan and security agreements executed with Hercules Capital, Inc.

(Hercules) (see Note 7 for more information), and the upfront payment from our commercialization agreement executed with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm) the Commercialization Agreement (see Note 112 for more information). 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. As of June 30, 2023September 30, 2023, we had generated $23.8 million $48.9 million in product revenue from drug sales of BRIUMVI. BRIUMVI first became commercially available in the United States in January of 2023. Even with the commercialization of BRIUMVI and the possible future commercialization of our other drug candidates, we may not become profitable. Our ability to achieve profitability depends on our ability to generate revenue and many other factors, including our ability to successfully commercialize our drug candidates alone or in partnership; successfully complete any post-approval regulatory obligations; and our ability to

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maintain or obtain regulatory approval for our drug candidates. We may continue to incur substantial operating losses even if now that we begin to generate are generating revenues from our drug candidates. BRIUMVI.

As of June 30, 2023September 30, 2023, we had $144.9 million $229.2 million in cash and cash equivalents, and investment securities. We anticipate that our The Company believes its existing cash, cash equivalents, and investment securities, as of June 30, 2023, combined with the upfront payment of $140.0 million in July 2023 as part of our commercialization agreement with Neuraxpharm and projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will provide be sufficient liquidity to fund its anticipated operating cash requirements for more than a twelve-month period from at least twelve months following the date of filing of this Quarterly Report on Form 10-Q. filing.

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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 2022 Annual Report on Form 10-K,10-K, except updated herein or as it relates to revenue recognition, accounts receivable, inventory, cost of product revenue, and the adoption of new accounting standards during the sixnine months ended June 30, 2023September 30, 2023. 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.

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-stepfive-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

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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.

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

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

Subject to certain limitations, the Company's return policy allows for eligible returns of 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 June 30, 2023September 30, 2023, 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).

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 June 30, 2023September 30, 2023, 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.

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Cost of Product Revenue

Cost of product revenue consists primarily of third-partythird-party manufacturing costs, distribution, overhead and royalties owed to our licensing partner for BRIUMVI sales. Cost of sales 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 product revenue. Our cost of revenue also relates to providing regulatory support & development services to customers.

Inventory

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

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

Net Loss Income (Loss) Per Common Share

Basic net loss income (loss) per share of our common stock is calculated by dividing net loss income (loss) applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss 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 were the same as basic net loss per share for all periods presented in the unaudited condensed consolidated statement of common stock since potentially dilutive securities from stock options, restricted stock, stock warrants operations, except for the three and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money andnine months ended September 30, 2023, as the Company realized had net income during the period presented. The cumulative amounts of potentially dilutive securities excluded from the calculation were 13,456,358 and 13,512,092 for the six months ended June 30, 2023 and 2022, respectively. those periods.

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The following table summarizes our potentially dilutive securities at June 30, 2023 September 30, 2023 and 2022:

	Six Months Ended June 30,

	2023	2022
Unvested restricted stock	8,324,240	10,004,825
Options	4,799,523	3,225,515
Warrants	312,272	262,100
Shares issuable upon note conversion	20,323	19,652
Total	13,456,358	13,512,092

2022:

	As of September 30,	
	2023	2022
Unvested restricted stock	8,454,545	10,901,797
Options	4,697,029	5,153,737
Warrants	312,272	262,100
Shares issuable upon note conversion	20,646	20,135
Total	13,484,492	16,337,769

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)	2023	2022	2023	2022
Net income (loss)	113,930	(35,818)	27,088	(145,341)
Weighted-average common shares outstanding	142,871,227	135,327,035	141,571,785	134,839,207
Dilutive effect of potential common shares	13,000,522	-	4,381,128	-
Weighted-average common shares outstanding assuming dilution	155,871,749	135,327,035	145,952,913	134,839,207
Net income (loss) per share - basic	0.80	(0.26)	0.19	(1.08)
Net income (loss) per share - diluted	0.73	(0.26)	0.19	(1.08)

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NOTE 2 NET PRODUCT REVENUE

Product revenue, net

For the three and sixnine months ended June 30, 2023September 30, 2023 our only source of product revenue has been from U.S. sales of BRIUMVI which we began shipping to our customers in January 2023. For the three and sixnine months ended June 30, 2022September 30, 2022 our only source of product revenue was from the U.S. sales of UKONIQ, which we began shipping to our customers in February 2021. The voluntary withdrawal of UKONIQ was voluntarily withdrawn from the U.S. market was announced on April 15, 2022. Effective May

31, 2022, UKONIQ was officially withdrawn from the market. effective May 31, 2022.

As of June 30, 2023September 30, 2023, approximately $3.8 million $6.1 million of estimated gross-to-net accruals have been recorded as a reduction of accounts receivable, net and within accounts payable and accrued expenses on the condensed consolidated balance sheets.

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 previously partnered (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 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.

In consideration for entering 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 $505.0 million. The consideration for the supply of BRIUMVI is reimbursement of cost plus a reasonable overhead, which the Company has determined approximates the price that a customer in the Territory would be willing to pay for these goods.

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) exclusive right to develop, sell, offer to sell and import the Product in the Territory (the "License"); (ii) development and regulatory activities ("Development and Regulatory Activities"); and (iii) the requirement to supply Neuraxpharm with the Licensed Product at certain agreed amounts (the "Supply of Licensed Product"). The Company determined that these three commitments represent distinct performance obligations for purposes of recognizing revenue and will recognize revenue as it fulfills these performance obligations.

The License to the Company's intellectual property represents a distinct performance obligation, therefore, the $140 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, 2023, the Company recognized Other Revenue of $0.7 million related to the Development and Regulatory Activities.

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, 2023, the

Company has an unconditional right to receive $6.8 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, therefore, as of September 30, 2023, $6.8 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. Any consideration related to sales-based royalties will be recognized when the related sales occur. No royalty revenue was recognized during the three and nine months ended September 30, 2023.

NOTE3 INVESTMENT SECURITIES

Our investments as of June 30, 2023September 30, 2023 and December 31, 2022December 31, 2022 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at June 30, 2023September 30, 2023 and December 31, 2022December 31, 2022:

	June 30, 2023			
(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 July 2023 and February 2024) (held-to-maturity)	$ 47,896	$ —	$ 579	$ 47,317
Total short-term investment securities	$ 47,896	$ —	$ 579	$ 47,317

	December 31, 2022			
	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 2023 and December 2023) (held-to-maturity)	$ 59,374	$ —	$ 1,053	$ 58,321
Long-term investments:				

Obligations of domestic governmental agencies (maturing between January 2024 and February 2024) (held-to-maturity)	12,404	—	429	11,975
Total short-term and long-term investment securities	$ 71,778	$ —	$ 1,482	$ 70,296

	September 30, 2023			
(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 2023 and March 2024) (held-to-maturity)	$ 78,257	$ 10	$ 243	$ 78,024
Total short-term investment securities	$ 78,257	$ 10	$ 243	$ 78,024

	December 31, 2022			
	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 2023 and December 2023) (held-to-maturity)	$ 59,374	$ —	$ 1,053	$ 58,321
Long-term investments:				
Obligations of domestic governmental agencies (maturing between January 2024 and February 2024) (held-to-maturity)	12,404	—	429	11,975
Total short-term and long-term investment securities	$ 71,778	$ —	$ 1,482	$ 70,296

NOTE4 INVENTORY

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NOTE 4 INVENTORY

The following table presents our inventory as of June 30, 2023September 30, 2023 (in thousands):

	June 30, 2023	September 30, 2023
Raw Materials	$ 24	$ 1,228
Work in Process	29,551	31,713
Finished Goods	659	612
Total Inventory	$ 30,234	$ 33,553

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. At June 30, 2023September 30, 2023, all of our inventory was related to BRIUMVI, which was approved by the FDA on December 28, 2022, December 28, 2022, at which time we

began to capitalize costs to manufacture BRIUMVI. The Company has not recorded any inventory write downs since that time. 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. No costs related to the manufacturing of BRIUMVI and the related material were incurred between the approval date and year end 2022, therefore, inventory is not included in the December 31, 2022December 31, 2022 condensed consolidated balance sheets. Inventory that is used for clinical development purposes is expensed to research and development expense when consumed. At June 30, 2023September 30, 2023, we determined that a reserve related to BRIUMVI inventory is not required. We currently use a limited number of third-partythird-party contract manufacturing organizations (CMOs) to produce our inventory.

NOTE5 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.

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-yearfive-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 June 30, 2023September 30, 2023 and December 31, 2022December 31, 2022, 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.

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We have no Level 1 or Level 2 instruments. Our Level 3 instrument amounts represent the fair value of the 5% Notes and related accrued interest. The following table summarizes the changes in Level 3 instruments during the sixnine months ended June 30, 2023September 30, 2023:

(in thousands)	
Balance at December 31, 2022	243
Interest accrued on face value of 5% Notes	286
Change in fair value of Level 3 liabilities	(24)
Balance at June 30, 2023	$ 505

(in thousands)	
Balance at December 31, 2022	243
Interest accrued on face value of 5% Notes	844
Change in fair value of Level 3 liabilities	(915)
Balance at September 30, 2023	$ 172

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

NOTE6 STOCKHOLDERS' STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to

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

On September 2, 2022, September 2, 2022, we filed an automatic "shelf registration" statement on Form S-3S-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 sixnine months ended June 30, 2023September 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. 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.

Equity Incentive Plans

The TG Therapeutics, Inc. 2022 Incentive Plan (the 2022 Incentive Plan) was approved by stockholders in June 2022 with 17 million 17,000,000 shares available to be issued, of which not more than 10 million 10,000,000 shares may be issued pursuant to "full-value awards." Full-value awards include any award other than an option or stock appreciation right and which is settled by the issuance of stock. As of June 30, 2023September 30, 2023, 4,611,910 4,856,672 shares of restricted stock and 2,272,500 options were outstanding and up to an additional 9,175,825 8,742,674 shares were available to be issued under the 2022 Incentive Plan.

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The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (the 2012 Incentive Plan) was approved by stockholders in June 2020. As of June 30, 2023September 30, 2023, 5,212,3615,097,904 shares of restricted stock and 2,527,0292,424,529 options were outstanding, and no additional shares were available to be issued under the 2012 Incentive Plan as the 2022 Incentive Plan is now the only active incentive plan.

Stock-based compensation expense included in the condensed consolidated statements of operations was $9.2 million and $7.0 million for the three months ended September 30, 2023 and 2022, respectively, and $28.5 million and $8.1 million for the nine months ended September 30, 2023 and 2022, respectively. The $19.49.2 million and $1.1 million for the six months ended June 30, 2023 and 2022, respectively. The $19.428.5 million for the sixthree and nine months ended June 30, 2023,September 30, 2023, respectively, is net of $1.3 million$0.8 million and $2.1 million of stock-based compensation expense that was capitalized into inventory. inventory, respectively.

Stock Options and Restricted Stock

The following table summarizes the activity for stock options and restricted stock for the sixnine months ended June 30, 2023September 30, 2023:

	Stock Options	Restricted Stock
Equity awards outstanding, beginning of year	5,135,685	8,732,286
Changes during the year:		
Granted	—	3,112,736
Exercised or vested	(143,656)	(1,921,285)
Expired or Forfeited	(192,500)	(99,466)

Equity awards outstanding, end of period	4,799,529	9,824,271

	Stock Options	Restricted Stock
Equity awards outstanding, beginning of year	5,135,685	8,732,286
Changes during the year:		
Granted	—	3,570,237
Exercised or vested	(246,156)	(2,209,888)
Expired or Forfeited	(192,500)	(138,059)
Equity awards outstanding, end of period	4,697,029	9,954,576

As of June 30, 2023September 30, 2023, total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized were as follows:

(in thousands)	Stock Options	Restricted Stock	Stock Options	Restricted Stock
Unrecognized compensation cost	$ 6,021	$ 42,500	$ 5,063	$ 36,978
Expected weighted-average period in years of compensation cost to be recognized	2.9	3.0	2.7	2.8

Warrants

The Company's only outstanding warrants are the warrants issued to Hercules as part of the Loan Agreement, the Amended Loan Agreement and the First Amendment (as such terms are defined below)(please refer to Note 7 – Loan Payable) 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. See Note 7 for further details. There will not be any ongoing stock compensation expense volatility associated with these warrants.

NOTE7 LOAN PAYABLE

On February 28, 2019February 28,2019 (the Closing Date), we entered into a term loan facility with Hercules Capital, Inc. (Hercules or Lender), which provided us with the capacity to borrow up to an aggregate principal amount of $60.0 million (Term Loan). The Term Loan is governed by a loan and security agreement, dated February 28, 2019February 28,2019 (the Loan Agreement), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the Closing Date. An additional $30.0 million under the Term Loan was previously available upon the completion of different milestones and time points that have now lapsed.

On December 30, 2021 (theDecember 30, 2021 (the Amended Loan Agreement Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules Capital, Inc. The Amended Loan Agreement amended the terms of the Loan Agreement to, among other things, (i) increase the aggregate principal amount of the loan, available at the Company's option, from $60.0 million to $200.0 million (the Amended Term Loan), (ii) issue a first advance of $70.0 million drawn at the Amended Loan Agreement Closing Date, a portion of which was used to refinance the current outstanding loan balance of approximately $7.8 million and pay for expenses incurred by the Lender in executing the agreements, (iii) change the draw amounts and dates available in subsequent tranches, (iv) extend the maturity date of the facility from the original March 1, 2022 March 1, 2022 to January 1, 2026, (v)January 1, 2026, (v) reset and extend the interest only

period from April 1, 2021 April 1, 2021 to February 1, 2025 February 1, 2025 and extendable to August 1, 2025 August 1, 2025 subject to the achievement of certain performance milestones, and (vi) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 2.15%, and (b) 5.40%. In addition to the cash interest rate, the principal balance accrues paid-in-kind interest at a rate of 3.45%, which amount will be capitalized and added to the outstanding principal balance of the Amended Term Loan and payable at the maturity date of the Amended Loan Agreement.

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On March 31, 2023 (theMarch 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended and Restated Loan and Security Agreement (the First Amendment) with Hercules. The First Amendment amended the terms of the Amended Loan Agreement to, among other things, (i) issue an advance of $25.0 million drawn at the First Amendment Effective Date (the Tranche 3A Advance), (ii) formal expiration of Tranche 2, (iii) change the draw amounts and dates available under subsequent tranches, including splitting the remaining balance of Tranche 3 into two additional advances in an aggregate principal amount of up to $20.0 million, in increments of $10.0 million (each a Tranche 3B Advance and Tranche 3C Advance), decreasing the amount available under Tranche 4 from $65.0 million to $60.0 million, and adding a Tranche 5 of $25.0 million, subject to the achievement of revenue related performance milestones, (iv) extend the interest only period from February 1, 2025 February 1, 2025 to August 1, 2025, August 1, 2025, and (v) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 1.20%, and (b) 8.95%. In addition to the cash interest

rate, the principal balance will accrue paid-in-kind interest at a rate of 2.25%, which amount will be capitalized and added to the outstanding principal balance of the Amended Term Loan and payable at the maturity date of the Amended Loan Agreement. The First Amendment requires contains financial covenants that require the company to maintain certain levels of unrestricted cash and additional financial covenants referenced above apply at related to market capitalization. As of September 30, 2023, we are in compliance with all times commencing on July 1, 2023. financial covenants.

The First Amendment also contains 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 for the amount funded pertaining to the Tranche 3A Advance (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.

In addition, the Company is required to pay a final payment fee equal to 5.95% of the aggregate principal amount of the Term Loan Advances (as defined in the Loan Agreement) plus 4.95% of the aggregate principal amount of all other advances.

The Company may, at its option, prepay the Amended Term Loan in full or in part, subject to a prepayment penalty equal to (i) 1.5% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the First Amendment Effective Date, and (ii) 1.0% of the principal amount prepaid if the prepayment occurs on or after the first anniversary of the First Amendment Effective Date.

The Company evaluated whether the First Amendment represented a debt modification or extinguishment of the Term Loan in accordance with ASC 470-50,470-50, Debt – Modifications and Extinguishments. As a result of the modification of terms and no

repayment or retirement of the Term Loan, the Term Loan was accounted for by the Company under the modification accounting model. The Company capitalized the facility charge from the First Amendment advance to debt issuance costs and expensed third party fees in the Company's statement of operations for the sixnine months ended June 30, 2023September 30, 2023.

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

	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 years

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The Company incurred financing expenses of $2.0 million (including the fair value of the First Amendment

Warrant) related to the First Amendment which are recorded as debt issuance costs and as an offset to loan payable on the Company's consolidated balance sheet. The debt issuance costs are being amortized over the term of the debt using the straight-line method, which approximates the effective interest method, and will be included in interest expense in the Company's consolidated statements of operations. Amortization of debt issuance costs was $1.1 million $0.6 million and $0.9 million $0.5 million for the sixthree months ended June 30, 2023, September 30, 2023, and 2022, respectively and $1.7 million and $1.4 million for the nine months ended September 30, 2023 and 2022, respectively. At June 30, 2023, September 30, 2022, the remaining unamortized balance of debt issuance costs was $6.4 $6.0 million. At September 30, 2023, the remaining unamortized balance of debt issuance costs was $5.8 million.

The loan payable as of June 30, 2023September 30, 2023 and December 31, 2022December 31, 2022, is as follows:

(in thousands)	June 30, 2023	December 31, 2022
Loan payable	$ 95,000	$ 70,000
Add: Accreted Liability of final payment fee	9,090	6,667
	104,090	76,667
Less: unamortized debt issuance costs	(6,390)	(5,532)
	97,700	71,135

Less: principal payments	—	—
Total loan payable	97,700	71,135
Less: current portion	—	—
Loan payable non-current	$ 97,700	$ 71,135

(in thousands)	September 30, 2023	December 31, 2022
Loan payable	$ 95,000	$ 70,000
Add: Accreted Liability of final payment fee	9,659	6,667
	104,659	76,667
Less: unamortized debt issuance costs	(5,751)	(5,532)
	98,908	71,135
Less: principal payments	—	—
Total loan payable	98,908	71,135
Less: current portion	—	—
Loan payable non-current	$ 98,908	$ 71,135

NOTE8 LEASES

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-yearfive-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 $0.1 million $0.2 million for the sixnine months ended June 30, 2023September 30, 2023.

In October 2021, we finalized a five-yearfive-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 $0.1 million for the sixnine months ended June 30, 2023September 30, 2023.

At January 1, 2019, January 1, 2019, we recognized a lease liability and corresponding Right-of-Use (ROU) asset of $9.5 million and $8.1 million, respectively, based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office

space. The present values of our lease liability and corresponding ROU asset are $11.3 million $11.0 million and $8.5$8.3 million, respectively, as of June 30, 2023September 30, 2023. Our leases have remaining lease terms of 2 years1 year to 98 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 sixnine months ended June 30, 2023 September 30, 2023 and 2022:2022:

(in thousands)	Three months ended June 30, 2023	June 30, 2022	Six months ended June 30, 2023	2022
Operating lease cost	$ 552	$ 524	$1,096	$1,038
Net lease cost	$ 552	$ 524	$1,096	$1,038

(in thousands)	Three months ended September 30, 2023	September 30, 2022	Nine months ended September 30, 2023	2022
Operating lease cost	$ 535	$ 1,062	$ 1,632	$ 2,100
Net lease cost	$ 535	$ 1,062	$ 1,632	$ 2,100

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As of June 30, 2023September 30, 2023, the weighted-average remaining operating lease term was 6.16.0 years and the weighted-average

discount rate for operating leases was 9.98% 9.99%. Cash paid for amounts included in the measurement of operating lease liabilities during the sixnine months ended June 30, 2023September 30, 2023 was $1.2 million. $1.8 million. The balance sheet classification of lease liabilities was as follows:

(in thousands)	June 30, 2023	December 31, 2022
Liabilities		
Lease liability current portion	$ 1,512	$ 1,581
Lease liability non-current	9,805	10,344
Total lease liability	$11,317	$ 11,925

(in thousands)	September 30, 2023	December 31, 2022
Liabilities		
Lease liability current portion	$ 1,479	$ 1,581
Lease liability non-current	9,522	10,344
Total lease liability	$ 11,001	$ 11,925

As of June 30, 2023September 30, 2023, the maturities of lease liabilities were as follows:

(in thousands)	Operating leases
Remainder of 2023	$ 1,188
2024	2,388
2025	2,100
2026	2,080
2027	1,913
After 2028	6,543

Total lease payments	16,212
Less: interest	(4,895)
Present value of lease liabilities(*)	$ 11,317

(in thousands)	Operating leases
Remainder of 2023	$ 594
2024	2,388
2025	2,100
2026	2,080
2027	1,913
After 2028	6,542
Total lease payments	15,617
Less: interest	(4,616)
Present value of lease liabilities(*)	$ 11,001

(*) 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,February 28,2019, for operating leases that commenced prior to that date through December 31, 2021. 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 June 30, 2023September 30, 2023, 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 future payments of up to an aggregate of approximately $12.0 million upon our successful achievement of certain regulatory milestones, in addition to royalty payments on net sales of ublituximab at a royalty rate that escalates from mid-single digits to high-single digits. The license will terminate on a country-by-country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is

earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party. During the three and sixnine months ended June 30, 2023September 30, 2023, the Company recorded $1.5 million$2.4 million and $2.3 million$4.8 million, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of product revenue based on U.S. sales of BRIUMVI. As of June 30, 2023September 30, 2023, $1.5 million$2.4 million in royalties were payable under the LFB License Agreement.

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In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong Pharmaceutical Co. Ltd. (Ildong) relating to the development and commercialization of ublituximab in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong

has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize ublituximab in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

An upfront payment of $2.0 million, which was received in December 2012, net of $0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately $38,000 for each of the three months ended June 30, 2023 September 30, 2023 and 2022 and

approximately $76,000$114,000 for each of the sixnine months ended June,September 30, 2023 and 2022. At June 30, 2023September 30, 2023 and December 31, 2022December 31, 2022, we have deferred revenue of approximately $0.4 million$0.3 million and $0.5 million, respectively, associated with this $2 million payment (approximately $0.2 million of which has been classified in current liabilities at June 30, 2023September 30, 2023 and December 31, 2022).December 31, 2022).

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.

UKONIQ (umbralisib)

In September 2014, we exercised our option to license the global rights to umbralisib, thereby entering into an exclusive licensing agreement (the Umbralisib License) with Rhizen

Pharmaceuticals, SA (Rhizen) for the development and commercialization of umbralisib. Prior to this, we had been jointly developing umbralisib in a 50:50 joint venture with Rhizen. As of June 30, 2023, we have incurred approximately $24.0 million in expense related to the achievement of certain milestones of the Umbralisib License.

Under the terms of the Umbralisib License, Rhizen is eligible to receive approval and sales-based milestone payments in the aggregate of approximately $175 million payable. Additionally, Rhizen receives tiered royalties that escalate from high single digits to low double digits on any net sales of umbralisib. During the year ended December 31, 2022, the Company recorded $0.2 million related to the worldwide royalty due under the Umbralisib License in cost of product revenue based on U.S. sales of UKONIQ and as of December 31, 2022, approximately $3,000 in royalties were payable under the Umbralisib

License. As of June 30, 2023, no royalties were payable under the Umbralisib License and as a result of the withdrawal of UKONIQ from the U.S. market and discontinuation of all commercialization activities, we do not expect to incur any additional costs related to this license agreement.

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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

$0.5 million and $0.4 million for the six months ended June 30, 2023 and 2022, 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.

NOTE 11 SUBSEQUENT EVENTS

In July 2023, the Company entered into an ex-U.S. commercialization agreement (the the Commercialization Agreement) Agreement with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm). 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,one-time,

non-refundable payment of $140.0 million upon contract execution. execution (please refer to Note 2 – Revenue). The Company is eligible to receive an additional $12.5 million upon first key market commercial launch in the EU and 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%. 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.

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

jointly developing umbralisib in a 50:50 joint venture with Rhizen. As of September 30, 2023, we have incurred approximately $24.0 million in expense related to the achievement of certain milestones of the Umbralisib License.

Under the terms of the Umbralisib License, Rhizen is eligible to receive approval and sales-based milestone payments in the aggregate of approximately $175 million payable. Additionally, Rhizen receives tiered royalties that escalate from high single digits to low double digits on any net sales of umbralisib. During the year ended December 31, 2022, the Company recorded $0.2 million related to the worldwide royalty due under the Umbralisib License in cost of revenue based on U.S. sales of UKONIQ and as of December 31, 2022, approximately $3,000 in royalties were payable under the Umbralisib License. As of September 30, 2023, no royalties were payable under the Umbralisib License and as a result of

the withdrawal of UKONIQ from the U.S. market and discontinuation of all commercialization activities, we do not expect to incur any additional costs related to this license agreement.

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NOTE10 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 $0.7 million and $0.6 million for the nine months ended September 30, 2023 and 2022, 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.

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ITEM2. MANAGEMENT'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited, condensed, consolidated financial statements and the related footnotes thereto appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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), RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. TG has also received approval for BRIUMVI by the EC 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 Updates Update Highlights

BRIUMVI Ex-U.S. Commercialization & Recent UK Approval

On August 1, 2023, we announced an agreement with Neuraxpharm, a leading European Commission Approval specialty

pharmaceutical company focused on the treatment of central nervous system (CNS) disorders, for the Ex-U.S. commercialization of BRIUMVI.

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.

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 October 2023.

Clinical Drug Candidate: (molecular target)	Initial Target Disease	Stage of Development (trial name)
Ublituximab (anti-CD20 mAb)	Relapsing Forms of Multiple Sclerosis (RMS)	APPROVED
TG-1701 (BTK inhibitor)	B-cell disorders	Phase 1 trial

TG-1801 (anti-CD47/CD19 bispecific mAb)	B-cell disorders	Phase 1 trial

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.**

- In addition to presenting various exploratory data sets from the ULTIMATE I & II trials at major medical meetings, on October 11, 2023 we also presented the first data from the ENHANCE Phase 3b trial evaluating RMS patients who switch from a IV anti-CD20 therapy to BRIUMVI at the 2023 European Committee for Treatment and Research in Multiple Sclerosis Annual Meeting.

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.

- Our commercialization efforts focused on engaging targeted neurology accounts with multi-channel promotional programming, sales engagements, infusion training and education. We also worked closely with payers to begin to secure insurance coverage for BRIUMVI. The first patient received a BRIUMVI infusion on February 1, 2023.
- On July 1, 2023, the permanent J-Code for BRIUMVI (J2329) became effective.

Ex-U.S. Commercialization Plans 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 European Union (EU) EU member states, Iceland, Norway and Liechtenstein.

On August 1, 2023, we announced an agreement with Neuraxpharm, a leading European specialty pharmaceutical company focused on the treatment of central nervous system (CNS) CNS disorders, for the ex-U.S. Ex-US commercialization of BRIUMVI. Under the terms of the commercialization agreement, we received an upfront payment of $140.0 million $140 million, and are eligible to receive an additional $12.5 million upon launch in the first EU country 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 United States, Canada and Mexico, which are retained by TG, and excluding certain Asian countries 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.

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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 July 2023.

Clinical Drug Candidate: (molecular target)	Initial Target Disease	Stage of Development (trial name)
Ublituximab (anti-CD20 mAb)	Relapsing Forms of Multiple Sclerosis (RMS)	APPROVED
TG-1701 (BTK inhibitor)	B-cell disorders	Phase 1 trial
TG-1801 (anti-CD47/CD19 bispecific mAb)	B-cell disorders	Phase 1 trial

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.

U.S. Commercialization of BRIUMVI

On December 28, 2022 November 1, 2023, we announced that we also received approval by the FDA approval of MHRA for BRIUMVI for to treat adult patients with RMS with active disease defined by clinical or imaging features in 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.

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- Our commercialization efforts focused on engaging targeted neurology accounts with multi-channel promotional programming, sales engagements, infusion training and education. We also worked closely with payers to begin to secure insurance coverage for BRIUMVI. The first patient received a BRIUMVI infusion on February 1, 2023.
- On July 1, 2023, the permanent J-Code for BRIUMVI (J2329) became effective.

For more information, please refer to our Annual Report on Form 10-K for the quarter and year ended December 31, 2022.

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RESULTS OF OPERATIONS

The following table summarizes the results of operations for the three

months ended June 30, 2023 September 30, 2023 and 2022:

(in thousands)	Three months ended June 30 2023	2022
Product revenue, net	$ 16,036	$ 556
License Revenue	38	38
Total Revenue	$ 16,074	$ 594
Costs and expenses:		
Cost of product revenue	1,911	23
Research and development:		
Noncash compensation	5,664	2,328
Other research and development	22,458	24,546
Total research and development	28,122	26,874
General and administrative:		
Noncash compensation	6,877	(3,304)
Other selling, general and administrative	23,838	15,942
Total general and administrative	30,715	12,638
Total costs and expenses	60,748	39,535
Interest expense	3,627	3,017
Other income	(691)	(1,448)
Total other expense, net	2,936	1,569
Net Loss	$ (47,610)	$ (40,510)

(in thousands)	Three months ended September 30, 2023	2022
Product revenue, net	$ 25,068	$ 56
License, milestone and other revenue	140,747	38
Total Revenue	$ 165,815	$ 94
Costs and expenses:		
Cost of revenue	3,509	2
Research and development:		
Noncash compensation	2,915	3,249
Other research and development	11,838	17,552

Total research and development	14,753	20,801
General and administrative:		
Noncash compensation	6,269	3,740
Other selling, general and administrative	26,500	10,514
Total general and administrative	32,769	14,254
Total costs and expenses	51,031	35,057
Interest expense	3,713	1,648
Other income	(2,859)	(793)
Total other expense, net	854	855
Net income (loss)	$ 113,930	$ (35,818)

Product Revenue, net. Product revenue, net was approximately $16.0 million $25.1 million for the three months ended June 30, 2023 September 30, 2023, compared to $0.6 million $0.1 million for the three months ended June 30, 2022 September 30, 2022. Product revenue, net for the three months ended June 30, 2023 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. Product revenue, net for the three months ended June 30, 2022 September 30, 2022, consisted of net product sales of UKONIQ, which was officially withdrawn from the market in May of 2022.

License Revenue. License revenue was $140.0 million and less than $0.1 million for both the three months ended June 30, 2023 September 30, 2023 and

June 30, 2022. September 30, 2022, respectively. License revenue for both the three months ended June 30, 2023 and June 30, 2022 September 30, 2023 is predominantly comprised of recognition of license revenue from the one-time payment under the Neuraxpharm Commercialization Agreement. License revenue for the three months ended September 30, 2022 is comprised of recognition of a portion of the upfront payment from the ublituximab sublicense agreement with Ildong.

Cost of ProductOther Revenue. Cost of product Other revenue was $0.7 million and zero for the three months ended September 30, 2023 and September 30, 2022, respectively. Other revenue for the three months ended June 30, 2023 was $1.9 million compared to approximately $23,000 September 30, 2023 is comprised of consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the three months ended June 30, 2022 Commercialization Agreement.

Cost of Revenue. Cost of product revenue for the three months ended June 30, 2023 September 30, 2023 was $3.5 million compared to approximately $2,000 for the three months ended September 30, 2022. Cost of revenue for the three months ended 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 product revenue. We expect the cost of product revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the end of 2024. Cost A portion of product the cost of revenue for the three months ended June 30, 2022 September 30, 2023 includes costs related to delivering regulatory support & development services to Neuraxpharm in accordance with the Commercialization Agreement. Cost of revenue for the three months ended September 30, 2022 primarily relates to freight and royalties owed to our licensing partner for UKONIQ sales.

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Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $5.7 million $2.9 million for the three months ended June 30, 2023 September 30, 2023, as compared to $2.3 million $3.2 million during the comparable period ended June 30, 2022. The increase in noncash compensation expense was primarily due to vesting of milestone-based grants and a decrease in forfeitures during the three months ended June 30, 2023 compared to the three months ended June 30, 2022 September 30, 2022.

Other Research and Development Expense. Other research and development expense decreased for the three months ended June 30, 2023 September 30, 2023, by approximately $2.0 million $5.8 million to $22.5 million $11.8 million as compared to the comparable period ended June 30, 2022 September 30, 2022.

The decrease in R&D expense during the three months ended June 30, 2023 September 30, 2023 was primarily attributable to reduced manufacturing expense and clinical trial related expenses. Prior to the approval of BRIUMVI, manufacturing costs pertaining to BRIUMVI were expensed to research and development expense in the period incurred, and following approval are reflected in inventory. These decreased costs were offset by license milestones incurred during the three months ended June 30, 2023.

Noncash Compensation Expense (Selling, General and Administrative). **Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $6.9 million $6.3 million for the three months ended June 30, 2023 September 30, 2023, as compared to $(3.3) million $3.7 million during the comparable period ended June 30, 2022 September 30, 2022. The increase in noncash compensation expense was primarily due to greater vesting of milestone-based equity grants and a decrease in forfeitures during the three months ended June 30, 2023 September 30, 2023 compared to the three months ended June 30, 2022 September 30, 2022. The three months ended June 30, 2022 included forfeitures in excess of noncash compensation expense recognized, which resulted in income recognized for the period.**

Other Selling, General and Administrative. **Other selling, general and administrative expenses totaled $23.8 million $26.5 million for the three months ended June 30, 2023 September 30, 2023, as compared to $15.9 million $10.5 million during the comparable period ended June 30, 2022 September 30, 2022. The increase was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the commercialization of BRIUMVI, as well as increase in advisory fees pertaining to the Commercialization Agreement with**

Neuraxpharm during the three months ended June, September, 30, 2023. 2023.

Interest Expense. Interest expense increased by $0.6 million $2.1 million to $3.6 million $3.7 million for the three months ended June 30, 2023 September 30, 2023, as compared to $3.0 million $1.6 million for the three months ended June 30, 2022 September 30, 2022. The increase is mainly due to greater interest expense related to the First Amendment to the Amended Loan Agreement.

Other Income. Other income decreased increased by $0.8 million $2.1 million to $0.7 million $2.9 million for the three months ended June 30, 2023 September 30, 2023 as compared to the three months ended September 30, 2022. The increase is mainly due to higher interest income received from our money market investments, as well as a research & development tax credit refund received by our Australian subsidiary during the three months ended September 30, 2023.

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The following table summarizes the results of operations for the six nine months ended June 30, 2023 September 30, 2023 and 2022:

	Six months ended June 30	
(in thousands)	2023	2022
Product revenue, net	$ 23,801	$ 2,534
License Revenue	76	76
Total Revenue	$ 23,877	$ 2,610
Costs and expenses:		
Cost of product revenue	2,768	260
Research and development:		
Noncash compensation	7,247	4,223
Other research and development	36,744	70,693
Total research and development	43,991	74,916
General and administrative:		
Noncash compensation	12,117	(3,077)
Other selling, general and administrative	46,666	36,324
Total general and administrative	58,783	33,247
Total costs and expenses	105,542	108,423

Interest expense	6,471	5,681
Other income	(1,295)	(1,971)
Total other expense, net	5,176	3,710
Net Loss	$ (86,841)	$ (109,523)

(in thousands)	Nine months ended September 30, 2023	2022
Product revenue, net	$ 48,868	$ 2,591
License, milestone and other revenue	140,823	114
Total Revenue	$ 189,691	$ 2,705
Costs and expenses:		
Cost of revenue	6,277	262
Research and development:		
Noncash compensation	10,162	7,471
Other research and development	48,581	88,246
Total research and development	58,743	95,717
General and administrative:		
Noncash compensation	18,386	663
Other selling, general and administrative	73,167	46,840
Total general and administrative	91,553	47,503
Total costs and expenses	156,573	143,482
Interest expense	10,184	7,329
Other income	(4,154)	(2,765)
Total other expense, net	6,030	4,564
Net income (loss)	$ 27,088	$ (145,341)

Product Revenue, net. Product revenue, net was approximately $23.8 million $48.9 million for the six nine months ended June 30, 2023 September 30, 2023, compared to $2.5 million $2.6 million for the six nine months ended June 30, 2022 September 30, 2022. Product revenue, net for the six nine months ended June 30, 2023 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. Product revenue, net for the six nine months ended June 30, 2022 September 30, 2022, consisted of net product sales of UKONIQ, which was officially withdrawn from the market in May of 2022.

License Revenue. License revenue was $140.1 million and less than $0.1 million for both the six nine months ended June 30, 2023 September 30, 2023 and June 30, 2022. September 30, 2022, respectively. License revenue for both the six nine months

ended June 30, 2023 and June 30, 2022 September 30, 2023 is predominantly comprised of recognition of license revenue from the one-time payment under the Neuraxpharm Commercialization Agreement. License revenue for the nine months ended September 30, 2022 is comprised of recognition of a portion of the upfront payment from the ublituximab sublicense agreement with Ildong.

Other Revenue. Other revenue was $0.7 million and zero for the nine months ended September 30, 2023 and September 30, 2022, respectively. Other revenue for the nine months ended September 30, 2023 is comprised of consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement.

Cost of Product Revenue. Cost of product revenue for the six nine months ended June 30, 2023 September 30, 2023 was $2.8 million $6.3 million compared to approximately $0.3 million for the six nine months ended June 30, 2022 September 30, 2022. Cost of product revenue for the six nine months ended June 30, 2023 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 product revenue. We expect the cost of product revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the end of 2024. Cost A portion of product the cost of revenue for the six nine months ended June 30, 2022 September 30, 2023 includes costs related to delivering regulatory support & development services to Neuraxpharm in accordance with the Commercialization Agreement. Cost of revenue for the nine months ended September 30, 2022 primarily relates to freight and royalties owed to our licensing partner for UKONIQ sales.

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Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $7.2 million $10.2 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $4.2 million $7.5 million during the comparable period ended June 30, 2022 September 30, 2022. The increase in noncash compensation expense was primarily due to vesting of milestone-based grants and a decrease in forfeitures during the six nine months ended June 30, 2023 September 30, 2023 compared to the three nine months ended June 30, 2022 September 30, 2022.

Other Research and Development Expense. Other research and development expense decreased for the six nine months ended June 30, 2023 September 30, 2023, by approximately $34.0 million $39.7 million to $36.7 million $48.6 million as compared to the comparable period ended June 30, 2022 September 30, 2022. The decrease in R&D expense during the six nine months ended June 30, 2023 September 30, 2023 was primarily attributable to reduced manufacturing expense and clinical trial related expenses. Prior to the approval of BRIUMVI, manufacturing costs pertaining to BRIUMVI were expensed to research and development expense in the period incurred, and following approval

are reflected in inventory. These decreased costs were offset by license milestones incurred during the six nine months ended June 30, 2023 September 30, 2023.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $12.1 million $18.4 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $(3.1) $0.7 million during the comparable period ended June 30, 2022 September 30, 2022. The increase in noncash compensation expense was primarily due to vesting of milestone-based grants and a decrease in forfeitures during the six nine months ended June 30, 2023 September 30, 2023 compared to the three nine months ended June 30, 2022 September 30, 2022. The six months ended June 30, 2022 included forfeitures in excess of noncash compensation expense recognized, which resulted in income recognized for the period.

Other Selling, General and Administrative. Other selling, general and administrative expenses totaled $46.7 million $73.2 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $36.3 million $46.8 million during the comparable period ended June 30, 2022 September 30, 2022. The increase was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the approval and commercialization of BRIUMVI, as well as increase in advisory fees pertaining to the Commercialization Agreement with Neuraxpharm Pharmaceuticals, S.L. during the six nine months ended June, September, 30, 2023. 2023.

Interest Expense. Interest expense increased by $0.8 million $2.9 million to $6.5 million $10.2 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $5.7 million $7.3 million for the six nine months ended June 30, 2022 September 30, 2022. The increase is mainly due to greater interest expense related to the First Amendment to the Amended Loan Agreement.

Other Income. Other income decreased increased by $0.7 million $1.4 million to $1.3 million $4.2 million for the six nine months ended June 30, 2023 September 30, 2023. The increase is mainly due to higher interest income received from our money market investments, as well as a research & development tax credit refund received by our Australian subsidiary during the nine months ended September 30, 2023.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash cash have been proceeds from private placement and public offering of equity securities, from our loan and security agreements executed with Hercules (see Note 7 for more information), and from our Commercialization Agreement executed with Neuraxpharm (see Note 11 2 for more information). Since inception,

Historically, we have incurred significant operating losses. losses since our inception; however, the Company experienced a net profit during the three and nine months ended September 30, 2023 due to a $140.0 million non-refundable upfront payment recognized as license revenue in the third quarter of 2023 as part of the Commercialization Agreement with Neuraxpharm. 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. As of June 30, 2023 September 30, 2023, we had generated $23.8 million $48.9 million in product revenue from drug sales of BRIUMVI. BRIUMVI first became commercially available in the United States in January of 2023. Even with the commercialization of BRIUMVI and the possible future commercialization of our other drug candidates, we may not become profitable. Our ability to achieve profitability depends on our ability to generate revenue and many other factors, including our ability to successfully commercialize our drug candidates alone or in partnership; successfully complete any post-approval regulatory obligations; and obtain regulatory approval for our drug candidates. We may continue to incur substantial operating losses even if now that we begin to generate are generating revenues from our drug candidates. BRIUMVI.

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As of June 30, 2023 September 30, 2023, we had $144.9 million $229.2 million in cash and cash equivalents, and investment securities. We anticipate that our The Company believes its existing cash, cash equivalents, and investment securities, as of June 30, 2023, combined with the upfront payment of $140.0 million received in July 2023 as part of our commercialization agreement with Neuraxpharm and projected revenues associated with the sale of BRIUMVI in the U.S. and

ex-U.S., will provide be sufficient liquidity to fund its anticipated operating cash requirements for more than a twelve-month period from at least twelve months following the date of filing of this Quarterly Report on Form 10-Q. 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 six nine months ended June 30, 2023 September 30, 2023 and 2022:

	Six months ended June 30	
(in thousands)	2023	2022
Net cash used in operating activities	$ (101,907)	$ (117,805)
Net cash provided by (used in) investing activities	$ 24,333	$ (33,292)
Net cash provided by (used in) financing activities	$ 72,285	$ (715)

	Nine months ended September 30,	
(in thousands)	2023	2022
Net cash used in operating activities	$ (18,203)	$ (152,300)
Net cash used in investing activities	$ (5,896)	$ (36,282)
Net cash provided by (used in) financing activities	$ 72,706	$ (440)

Cash used in operating activities for the six nine months ended June 30, 2023 September 30, 2023 was $101.9 million $18.2 million as compared to $117.8 million cash used in operating activities of $152.3 million for the six nine months ended June 30, 2022 September 30, 2022. The decrease in net cash used in operating activities was due primarily to less expenditures associated with our manufacturing and clinical trial expenses the one-time upfront payment of $140.0 million from Neuraxpharm, as part of the Commercialization Agreement during the six nine months ended June 30, 2023 September 30, 2023.

Net cash provided by investing activities for the six months ended June 30, 2023, was $24.3 million as compared to cash used in investing activities of $33.3 million for the six nine months ended June 30, 2022 September 30, 2023, was $5.9 million as compared to $36.3 million for the nine months ended September 30, 2022. The increase decrease in net cash provided by used in investing activities was primarily due to decreased investment in short-term and long-term securities as well as the maturity of investments during the six nine months ended June 30, 2023 September 30, 2023.

Net cash provided by financing activities for the six nine months ended June 30, 2023 September 30, 2023, was $72.3 million $72.7 million as compared to net cash used in financing activities of $0.7 million $0.4 million for the six nine months ended June 30, 2022 September 30, 2022. The increase in net cash provided by financing activities was primarily due to the advance of $25.0 million drawn as part of the First Amendment entered into with Hercules, on March 31, 2023 and $46.3 million received in net proceeds under the 2022 ATM.ATM during the nine months ended September 30, 2023.

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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 2022 Annual Report on Form 10-K and refer to Note 1 in this Quarterly Report on Form 10-Q for significant accounting policies due to commercialization for revenue recognition, gross-to-net sales adjustments, accounts receivable, inventory, and cost of product revenue. Of these policies, the following are considered critical to an understanding of our Unaudited Condensed Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments: stock-based compensation expenses, and fair value measurement of financial liabilities. Refer to "Note 2 – Net Product Revenue" –Revenue", "Note 5 - Fair Value Measurements" and "Note 6 – Stockholders' Equity" respectively, for more information.

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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, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2023 September 30, 2023, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2023 September 30, 2023, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2023 September 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PARTII. OTHER INFORMATION

ITEM1. LEGAL PROCEEDINGS

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

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ITEM 1A. RISK RISK FACTORS.

You should carefully consider the following risk factors and the other information contained elsewhere in this Annual 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.

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 U.S. 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, for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features.

While we have initiated the commercial launch of BRIUMVI in the U.S., 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.

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In addition, the COVID-19 pandemic 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 COVID-19 or lead to more severe complications or outcomes upon infection, including death. These 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 limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the approved product candidate. For example, with respect to the FDA's approval of BRIUMVI for RMS, maintenance of this 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 Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (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.

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.

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

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

The incidence and prevalence for target patient populations of BRIUMVI and our product candidates, including TG-1701 and TG-1801 in B-cell disorders, 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 of 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 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.

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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 neurology and immunology, 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 (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.

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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. As of April 27, 2023, we received a product-specific J-Code for BRIUMVI (J2329), which went effective July 1, 2023, and is expected to help reduce reluctance by physicians to prescribe BRIUMVI based on reimbursement concerns. However, some third-party payors nevertheless may 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.

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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 any 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 UKONIQ in the U.S. Although we withdrew UKONIQ from sale, we are using and expanding upon many of those systems and processes to market 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 ability 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 with, 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. 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 territories outside the U.S., Canada, and Mexico, which are retained by TG, and excluding certain Asian countries previously partnered, and 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.

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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. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and anticipate that we will may incur continued losses for in the foreseeable 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 pre-clinical studies and clinical trials, commercializing UKONIQ (which we withdrew 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 product and product candidates, 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. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had, and will continue to have an adverse effect on our stockholders' deficit and working capital. BRIUMVI is currently our only marketed product. We expect to continue to incur significant research and development expenses and we expect to continue to incur significant commercialization and outsourced-manufacturing expenses as we commercialize BRIUMVI. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

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We have not generated any significant revenue from the sale of our product. To become and remain profitable, we must succeed in developing (or in-licensing) and commercializing our products or products candidates that generate significant revenue. It is uncertain when and if we will 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 product and product candidates; and (ii) manufacturing and marketing 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 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; 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 profitable and we will be unable to continue our operations without continued funding.

WeWhile we don't expect to need to raise additional capital, we may need to raise substantial additional funding. do so. If we are unable to raise capital, when 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 currently advancing our early-stage drug candidates, TG-1701 and TG-1801 in ongoing Phase 1 studies to identify tolerable and efficacious doses. We are also continuing to generate additional clinical data for BRIUMVI to support and potentially expand commercial adoption, including assessing long-term tolerability in an 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. Moreover, now that we have launched BRIUMVI, we will need to expend substantial resources on maintaining approvals, continuing commercialization, manufacturing and distribution over the foreseeable future.

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 will be required. Additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds

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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 loan and security agreement that we entered into with Hercules in February 2019, expanded in December 2021, and amended on March 31, 2023 (*see* Note 7 to our consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or 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.

Long-term commercialization and product candidate development timelines and projections in this report are based on the assumption of further financing.

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

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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 Amendment Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules. Under the Amended Loan Agreement, Hercules increased the aggregate principal amount of the loan, available at the Company's option, from $60.0 million to $200.0 million. On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended and Restated Loan and Security Agreement (the First Amendment) with Hercules. An advance of $25.0 million was drawn at the First Amendment Effective Date (*see* Note 7 to our consolidated financial statements for more information). We have the option to request an additional $20.0 million under the First Amendment, such option will lapse if not elected by September 15, 2023. We have the option to request additional loan advances, in an aggregate principal amount of up to $85.0 million under the First Amendment.

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

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

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

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

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

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

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

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

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 do 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 obtain and maintain 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;
- INDs
  Investigational new drugs (INDs) and clinical trial applications (CTAs), being cleared/approved such that our product candidates can commence clinical trials;
- successful initiation and completion of preclinical studies and successful initiation of, enrollment in, and completion of clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;

- receipt of regulatory approvals from applicable regulatory authorities for our product candidates;
- 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," "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 pre-clinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

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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 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 given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the

conclusions we have reached, our ability to obtain approval for, or successfully commercialize, our product 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.

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

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. It is impossible to predict when or if our product candidates will prove effective and safe in humans, 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 an NDA a New Drug Application (NDA) or a BLA 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, such as the COVID-19 pandemic, that could delay or prevent our ability to complete current clinical trials, initiate new trials, receive marketing approval or commercialize our product candidates, including:

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

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises, such as the COVID-19 pandemic, international conflicts such as the Russian invasion of Ukraine, economic instability, or natural disasters;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs or ECs to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other therapies in the same or a similar class that raise safety or efficacy concerns about our product candidates.

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

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

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

Our product 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.

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

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

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

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 product candidate until we receive approval of a BLA or NDA from the FDA. The process of obtaining a BLA or NDA approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, approval policies or regulations may change over time. If we fail to gain approval to commercialize our product candidates from the FDA and other foreign regulatory authorities in the timelines we project or at all, we may be unable to generate the revenues that we may project or generate revenues at levels sufficient to sustain our business.

The FDA and foreign regulatory authorities have substantial discretion in the pharmaceutical product approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. During the regulatory review process, the FDA or other regulatory authorities may disagree with or not accept our clinical trial design, may have questions about the potential impact of our study design on conclusions that can be drawn from the data, may interpret results differently than we do, 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 that has received a Special Protocol Assessment (SPA). There is no guarantee that the FDA will not delay, limit or deny approval of our product candidates in the future.

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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 is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies and/or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other marketing authorization submission to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for commercial supplies; during the course of review, the FDA or foreign regulatory authorities may raise issues and request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC), or other data and information, and the development and provision of these data and information may be time consuming. We may not be able to generate the data within the time period necessary to obtain approval within the established regulatory review timelines, such as by a PDUFA goal date or at all to satisfy the FDA or foreign regulatory authorities;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; or
- interruptions or delays in the operations of the FDA and foreign regulatory authorities as a result of global health or economic crises, such as the COVID-19 pandemic, international conflict, or national disasters may negatively impact review, inspection, and approval timelines.

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

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

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

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.

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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 the FDA may not accept data from 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. The geographic variability of the COVID-19 pandemic also introduces increased risk in the conduct of clinical research in certain countries and territories where vaccination rates and available standard of care anti-viral therapy varies significantly. Such problems, if they were to occur, could negatively impact trial results, and depending on the circumstances and scope of concerns could potentially even prevent a trial from being useful or acceptable for regulatory approval. If such events were to occur with respect to any of our trials (and in particular with respect to registration-directed studies), they would have a substantial negative impact on our business.

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 these territories, 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 new 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.

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 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, 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 many years. 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. Both 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 (DEA) if applicable, and corresponding state agencies to ensure strict compliance with cGMP 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 pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity and/or analytical profile of the product 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.

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.

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There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, limit price increases, evaluate the relationship between pricing and manufacturer patient programs, and reform government health care program reimbursement methodologies for prescription drugs. For example, the Bipartisan Budget Act of 2018 (the BBA) increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70% effective as of January 1, 2019, ultimately increasing the liability for brand drug manufacturers. We expect that health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria, 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.

Most recently, 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 (the DHHS) to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs to be selected by September 1, 2023 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, and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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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.

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 and EMA 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 Federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute or the Federal Food, Drug, and Cosmetic Act constitutes a false or fraudulent claim for purposes of the False Claims Act;

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- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the so-called federal "Sunshine Act" under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to monitor and report 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
  - the Federal Food, Drug, and Cosmetic Act and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;
  - federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
  - the Drug Supply Chain Security Act (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.

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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, various federal and state laws regulate the privacy and security of personal information and so may affect our business operations. For example, at the federal level, our operations may be affected by the data privacy and security provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations. 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 (the FTCA), the FTC 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. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act (the CCPA), went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. Colorado, Connecticut, Utah, Virginia and Iowa have also enacted data privacy statutes, and both California and Colorado are also undergoing or have undergone rulemaking procedures to finalize regulatory regimes to supplement their privacy statutes.

Numerous other jurisdictions regulate the privacy and security of personally identifiable data. For example, the processing of personal data in the European Economic Area (the 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.

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

management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

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

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

Any product for which we obtain marketing approval, 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.

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's 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 releases.

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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 CMOs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory

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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 pre-clinical 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.

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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 on-going operations and entail curtailing other important research and development or commercialization efforts, all of which could have a material adverse effect on the Company. 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.

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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 such as the COVID-19 pandemic or natural disasters that may cause those suppliers to stop work for a period of time or lead to a sudden increase in demand for selected materials resulting in short-term unavailability of such materials. If any of our suppliers ceases its operations for any reason or is unable or unwilling to supply starting materials, intermediates, API/drug substance, and drug product in sufficient quantities or on the timelines necessary to meet our needs, it could significantly and adversely affect our business, the supply of our drug candidates and our financial condition. In addition, if our current or future supply of any of our products or product candidates should fail to meet specifications during its stability program there could be a voluntary or mandatory product recall if the product is approved and, even in the absence of a recall, there could be significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product.

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.

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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.

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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. 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:

- our collaboration and commercialization partners may 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 was to terminate 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 other 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 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 their 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.

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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 expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA, 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 acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from their sales.

Risks Relating to Our Intellectual Property

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

Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to any product we commercialize, including 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

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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.

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In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to some of the pending patent applications covering our drug candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO 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.

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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 will prove inadequate.

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

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

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

If we do not obtain patent term extensions under the Hatch-Waxman 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 14 years from the date of product approval by the FDA, and only one patent covering the approved product may be extended.

The application for a patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of the patent protection afforded could be less than 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.

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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.

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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.

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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-

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consuming, 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.

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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. In January and April 2022, following the withdrawal of the BLA and sNDA supplemental New Drug Application (sNDA) for U2 the combination of ublituximab and UKONIQ (combination referred to as U2) and the withdrawal of UKONIQ from sale, we engaged in streamlining efforts across the Company, reducing headcount and external expenses, primarily related to our oncology commercialization and research and development functions. Those streamlining efforts have made and may continue to make retention of key personnel more difficult. 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 July 25, 2023 November 1, 2023, we had 244 245 full-time 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.

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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.

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2022, we had federal net operating loss carryforwards of approximately $1.3 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.

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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' 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 closure 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.

Furthermore, the COVID-19 pandemic has caused extreme volatility and disruptions in the capital and credit markets. Likewise, the capital and credit markets may be adversely affected by the conflict between Russia and Ukraine, the possibility of a wider European or global conflict, and 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 begun the process of removing or reducing monetary accommodation, increasing the risk of recession and may also negatively impact asset values and credit spreads that were impacted 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.

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

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

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

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

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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.

The COVID-19 pandemic could have a material adverse effect on our business if new variants continue to circulate and government control measures are reinstated.

The COVID-19 pandemic presented substantial public health challenges and negatively impacted the global economy, global supply chains, and the global healthcare system, including the conduct of clinical trials in the U.S. and other parts of the world. New variants continue to circulate, and uncertainty remains as to whether restrictions that have been lifted will be reinstated or new measures will be implemented to address the spread of new variants. The extent to which the COVID-19 pandemic continues to impact our business and operating results will depend on future developments that cannot be accurately predicted. Should the COVID-19 pandemic worsen and government restrictions be reinstated, our business operations could be materially delayed or interrupted. For instance, our supply chain may be disrupted; health authority inspections of clinical sites, marketing application sponsor, CROs, or manufacturing facilities or review of our regulatory submissions may be delayed; and our commercialization efforts may be impacted.

In addition, we may encounter delays in our clinical development program. The majority of our clinical trials involve patients with multiple sclerosis who may be at higher risk of infection. These patients are thus more likely to be subject to travel restrictions and self-quarantining and may be more likely to withdraw from our clinical trials or unable to complete study assessments, which may affect our ability to meet our projected timelines. Further, patients and healthcare providers have raised concerns that B-cell targeted agents, like anti-CD20 antibodies, may increase the risk of acquiring COVID-19 or lead to more severe complications or outcomes upon infection, including death, which could have a material adverse effect on our product and product candidates by negatively impacting, among other things:

- the results of clinical trials;
- the regulatory review and approval;
- the labeling, if approved, including restrictions on use or other warnings, or
- the acceptance of our product among patients, healthcare providers, and payors, if approved.

The pandemic also may adversely affect our ability to complete ongoing clinical trials or conduct new trials. We will continue to monitor the potential impact of COVID-19 on our business; however, the full extent to which the COVID-19 pandemic may directly or indirectly impact the progress of our current and planned trials will depend on future developments that are uncertain and cannot be accurately predicted.

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' investors' ability to sell stock at a profit.

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

- reception and success of BRIUMVI in the U.S. market;
- the anticipated launch of BRIUMVI in 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;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors such as the disruptions in the global economy caused by the COVID-19 pandemic and the conflict between Russia and Ukraine;
- period-to-period fluctuations in our revenues and other results of operations;
- failure to meet our revenue projections or guidance;
- changes in financial estimates by securities analysts; and
- sales of our common stock by us.

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

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

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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 to effectively respond to changes in, or new, 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.

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

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

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

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

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

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. 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.

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

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

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

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

Not applicable.

ITEM 3. DEFAULTS OF SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHERINFORMATION. INFORMATION.

Securities Trading Plans of Directors and Executive Officers

During the three months ended June 30, 2023 September 30, 2023, 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.

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ITEM 6. EXHIBITS

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

10.1*		Commercialization Agreement by and between TG Therapeutics, Inc. and Neuraxpharm Pharmaceuticals, S.L., dated as of July 28, 2023. +
	31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 4, 2023 November 6, 2023.
	31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 4, 2023 November 6, 2023.
	32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 4, 2023 November 6, 2023.

32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 4, 2023 November 6, 2023.
101*	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023 September 30, 2023, 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 Operations, (iii) Changes in Stockholders' Equity, (iv) the Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) Cash Flows, and (v) Notes to 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).

104*

Cover Page Interactive Data File (embedded within the Inline XBRL document).

*** Filed herewith.**

**** Furnished herewith.**

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

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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.

E-Mail: [***]

TG THERAPEUTICS, INC.

Date: August 4, 2023 November 6, 2023 **By: /s/ Sean A. Power**

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

Exhibit 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]."

COMMERCIALIZATION AGREEMENT

This COMMERCIALIZATION AGREEMENT (this "*Agreement*") is entered into as of July 28, 2023 (the "*Effective Date*") by and between TG Therapeutics, Inc., a Delaware corporation ("*TG Parent*"), and TG Biologics, Inc.,

a Delaware corporation (f/k/a TG Therapeutics, Inc.) (together with TG Parent, "*TG*"), on the one hand, and Neuraxpharm Pharmaceuticals S.L., a private limited company incorporated under the laws of Spain ("*Company*"), on the other hand. Each of TG and Company is sometimes referred to individually herein as a "*Party*" and collectively as the "*Parties*".

RECITALS

WHEREAS, TG is engaged in the research, development, and commercialization of pharmaceutical products targeting B-cell disease;

WHEREAS, TG has developed, and is developing, a pharmaceutical product containing an investigational CD20 targeting antibody that treats multiple sclerosis;

WHEREAS, TG desires to grant Company, and Company desires to accept from TG, an exclusive license to commercialize the Product in the Field in the Territory (each, as defined below), on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 shall have the meanings specified.

1.1 **"[***]-[***] *Commercialization Plan*" has the meaning set forth in Section 5.1.**

1.2 **"*Action*" has the meaning set forth in Section 10.5.1(c).**

1.3 **"*Adverse Event*" means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered the Compound or Product, whether or not considered related to such Compound or Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom, or disease associated with the use of the Compound or Product, or an otherwise noxious and unintended response to the Compound or Product, including as defined more fully in 21 CFR §312.32 and Art. 2 m) of Directive 2001/20/EC.**

1.4 **"*Affiliate*" means, with respect to any Person, any other Person that, directly or indirectly, controls, or is controlled by, or is under common control with, such Person. For**

purposes of this definition, "control" means (a) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, (or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited); (b) status as a general partner in any partnership; or (c) any other arrangement whereby a Person controls or has the right to control the board of directors of a corporation or equivalent governing body of an entity other than a corporation. Notwithstanding the foregoing, Affiliates of Company shall not include Persons that would otherwise be deemed an Affiliate solely as a result of their being the portfolio companies (except for the Company as well as the other companies of the Neuraxpharm group) of the Permira branded funds managed or advised by Permira Beteiligungsberatungs GmbH (or one of its Affiliates) (collectively, the "*Other Permira Companies*"); provided, however, that, for the avoidance of doubt, in the event that Company undergoes a Change of Control, the foregoing exception for Other Permira Companies shall automatically be deemed to be deleted and the general terms of the definition of Affiliate without such exception shall determine whether any such Person qualifies as an Affiliate of Company.

1.5 **"*Agreed % of Net Sales*" has the meaning set forth in Section 7.3.**

1.6 **"*Annual Net Sales*" means, with respect to any Calendar Year, the aggregate amount of Net Sales for such Calendar Year.**

1.7 **"*Applicable ABC Laws*" has the meaning set forth in Section 12.3.6.**

1.8 **"*Applicable Laws*" means any national, international, federal, state, or local laws, treaties, statutes, ordinances, rules, and regulations, including any rules, regulations, guidance, or guidelines of Regulatory Authorities having the binding effect of law, or of any national securities exchanges or securities listing organizations or other government authorities other than Regulatory Authorities, that are in effect from time to time during the Term and applicable to a particular activity hereunder.**

1.9 **"*Arising IP*" means any Technology, Proprietary Material, and/or other intellectual property arising from or otherwise conceived and reduced to practice (actually or constructively), developed, or generated as a result of or in connection with the activities contemplated by this Agreement, whether by either Party or jointly, or by Company's Affiliate(s), Sublicensee(s), and/or**

Distributor(s), and whether or not patentable, copyrightable, or otherwise protectable under any intellectual property rights.

1.10 **"*Bankruptcy Code*" has the meaning set forth in Section 11.3.**

1.11 **"*Biosimilar Product*" means a product that is developed and commercialized by a Third Party, without any involvement (contractual or otherwise) of Company and/or any of its Affiliates, (a) in countries in the European Union, that (i) is a highly similar version of the Product, (ii) is a biological medicinal product with no clinically meaningful differences from the Product and is similar to the Product in terms of structure, biological activity and efficacy, safety, and immunogenicity profile without meeting the conditions in the definition of "generic medicinal products" under and in accordance with Art. 10 (2) (b) of Directive 2001/83/EC, owing to, in**

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particular, differences relating to raw materials or differences in manufacturing processes of the Biosimilar Product and the Product under and in accordance with Art. 10 (4) of Directive 2001/83/EC, and (iii) is approved for use in the Field in the European Union by an abbreviated marketing authorization process that relies on the Product, as the original or reference medicinal product under and in accordance with Art. 10 (2) (a) of Directive 2001/83/EC, or (b) in countries in the Territory other than the European Union, a biological product that the applicable Regulatory Authority has determined is a biosimilar to the Product, meaning it is highly similar to and has no clinically meaningful differences from the Product, and is approved by an abbreviated marketing authorization process that relies on the first Marketing Authorization of the Product, as the original or reference biological product as to which the determination of biosimilarity is made ("*Reference Medicinal Product*"), and that is approved for use in the Field.

1.12 **"*Brand Guidelines*" has the meaning set forth in Section 2.1.3(d).**

1.13 **"*Branding*" means all matters relating to the branding of the Product in the Field in the Territory, including any matters related to the selection of any trademarks, brand names, product logos, branding colors, trade dress, positioning, and key messages to be**

incorporated into Promotional Materials used for the Product in the Field in the Territory.

1.14 **"*Business Day*" means any day other than a Saturday or Sunday on which banking institutions in New York, New York are open for business.**

1.15 **"*Buy-Back Option*" has the meaning set forth in Section 11.2.5.**

1.16 **"*Calendar Quarter*" means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31; provided, that, the final Calendar Quarter shall end on the last day of the Term.**

1.17 **"*Calendar Year*" means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) consecutive months commencing on January 1 and ending on December 31; provided, that, the final Calendar Year shall end on the last day of the Term.**

1.18 **"*Challenge*" means any challenge to the validity or enforceability of any of the Licensed Patent Rights or Arising IP before any administrative, judicial, or other governmental authority, court, tribunal, or arbitration panel, including by (a) filing a declaratory judgment action in which any of the Licensed Patent Rights or Arising IP is alleged to be invalid or unenforceable; (b) citing prior art, filing a request for re-examination of any of the Licensed Patent Rights or Arising IP, or provoking or becoming a party to an interference with an application for any of the Licensed Patent Rights or Arising IP, or analogous proceedings in the Territory; or (c) filing or commencing any re-examination, opposition, cancellation, nullity, or similar proceedings against any of the Licensed Patent Rights or Arising IP in any country.**

1.19 **"*Change of Control*" means, with respect to either Party, a transaction or series of related transactions (including any merger, consolidation, share exchange, reorganization, or combination) involving such Party and any Third Party that results in (a) the holders of outstanding**

voting securities of such Party immediately prior to such transaction ceasing to represent at least fifty percent (50%) of the combined outstanding voting power of such Party or of the surviving or continuing entity immediately after such transaction or series of transactions; (b) any Third Party (other than a trustee or other fiduciary holding securities under an employee benefit plan) becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party (including as a single Third Party all persons who in concert or act together as a "group" for purposes of acquiring shares of such Party, in accordance with Section 13(d) of the Securities Act of 1934) (other than an investment transaction by an entity not engaged in the pharmaceutical or biotechnology business, the purpose of which is to raise capital for such Party); or (c) the sale or other disposition to a Third Party of all or substantially all of such Party's assets.

1.20 **"*Claims*" has the meaning set forth in Section 13.1.**

1.21 **"*Clinical Data*" means any and all data (together with all Clinical Trial reports and the results of analyses thereof) derived or generated from any Clinical Trial of the Compound or Product or from testing of subjects or the analysis of samples used in any such Clinical Trial.**

1.22 **"*Clinical Trial*" means, collectively, any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, Pivotal Clinical Trial, and/or Post-Approval Clinical Trial, as applicable.**

1.23 **"*CoC Agreement*" has the meaning set forth in Section 11.2.5.**

1.24 **"*Commercial Years*" has the meaning set forth in Section 5.4.1.**

1.25 **"*Commercialization*" or "*Commercialize*" means any and all activities directed to the offering for sale and sale of a product after Marketing Authorization has been obtained with respect to such product, including (a) activities directed to marketing, promoting, detailing, distributing, importing, selling, and offering to sell such product (but, for clarity, not including studies to support Product positioning and/or market penetration); (b) interacting with Regulatory Authorities regarding any of the foregoing; and (c) seeking Pricing Approvals and Reimbursement Approvals for such product. When used as a verb, "*to Commercialize*" and "*Commercializing*" means to engage in Commercialization and "*Commercialized*" has a corresponding meaning.**

1.26 **"*Commercialization Plan*" means each written report that (a) describes the Commercialization activities that Company reasonably expects to conduct with respect to the Product in the Field in the Territory, and (b) sets forth (i) a non-binding estimate of projected sales of the Product in the Field in the Territory, and (ii) a summary of all actual sales of the Product in the Field in the Territory. Without limiting the foregoing, each Commercialization Plan shall include, without limitation, (w) demographics and market dynamics, market strategies, and a marketing plan (including advertising, detailing forecasts, Pricing strategies pertaining to discounts, and sales forecasts) for the Product in the Field in the Territory; (x) specific Commercialization and marketing objectives, projected milestones, resource allocation requirements, and activities to be performed over such period (including all anticipated Territory-Specific Requirements and including the anticipated launch of the Product in the Field in any countries or regions in the Territory) (collectively, the "*Commercialization Targets*"); (y) a**

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timeline for such activities, including the estimated launch date of such Product in the Field in each country or region of the Territory; and (z) a sales and expense forecast (including at least [***]) for the Product in the Field in the Territory.

1.27 **"*Commercialization Report*" has the meaning set forth in Section 5.7.**

1.28 **"*Commercially Reasonable Efforts*" means, with respect to the activities of Company (and/or its Affiliates, Sublicensees, and Distributors), in the Development or Commercialization, as the case may be, of the Product, the level of efforts and resources typically used and expected from a pharmaceutical company for the development or commercialization of products of comparable market potential, which such products are fully owned by such pharmaceutical company without the obligation to compensate any third party in connection with such commercial exploitation (including profit sharing and other arrangements), taking into account all relevant factors including, as applicable: the stage of development; observed efficacy and safety of the Product, including as relative to other anti-CD20 monoclonal antibodies in the Field in the marketplace; actual or anticipated Regulatory Authority approved labeling; the nature and extent of**

market exclusivity (including patent coverage, regulatory exclusivity, and competitiveness of alternative products); the cost and likelihood of obtaining Marketing Authorization; the actual or projected profitability; and the reasonably expected and actual pricing, reimbursement, and formulary status; and without considering Company's and/or its Affiliates', Sublicensees', and Distributors' internal development and/or commercialization programs or its particular circumstances. For purposes of clarity, Commercially Reasonable Efforts shall be determined on a market-by-market basis for the Product, and it is anticipated that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the Product and the market(s) involved.

1.29 **"*Company Data*" has the meaning set forth in Section 3.7.**

1.30 **"*Company Development Activities*" has the meaning set forth in Section 3.1.3.**

1.31 **"*Company Employees*" means any employee, officer, agent, agency personnel, or any other person acting for or on behalf of Company or otherwise under Company's control or direction who is wholly or mainly assigned to providing Commercialization activities and/or Company Development Activities.**

1.32 **"*Company Indemnities*" has the meaning set forth in Section 13.2.**

1.33 **"*Company Persons*" has the meaning set forth in Section 12.3.6.**

1.34 **"*Competitive Program*" means any program that involves the research, development or commercialization of any (a) [***] or (b) [***].**

1.35 **"*Compound*" means the CD20 targeting antibody referred to as ublituximab (CAS 1174014-05-1), previously known as TG-1101 or LFB-R603.**

1.36 **"*Confidential Information*" means with respect to each Party, all information, Technology, and Proprietary Materials that is disclosed or provided by or on behalf of such Party (the "*Disclosing Party*") to the other Party (the "*Receiving Party*") or to any of the Receiving**

Party's employees, consultants, Affiliates, or sublicensees, or that is otherwise developed under this Agreement; provided, that, none of the foregoing shall be Confidential Information if: (a) as of the date of disclosure, it is known to the Receiving Party or its Affiliates as demonstrated by contemporaneous written documentation maintained in the ordinary course of business, other than by virtue of a prior confidential disclosure to such Receiving Party; (b) as of the date of disclosure it is in the public domain, or it subsequently enters the public domain through no fault of the Receiving Party; (c) it is obtained by the Receiving Party from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (d) it is independently developed by or for the Receiving Party without reference to or use of any Confidential Information of the Disclosing Party as demonstrated by contemporaneous written documentation maintained in the ordinary course of business. For purposes of clarity, (w) unless excluded from Confidential Information pursuant to the preceding sentence, any scientific, technical, manufacturing, or financial information of a Party that is disclosed through any report (including any audit report) shall constitute Confidential Information of the Disclosing Party; (x) all Clinical Data disclosed to Company as part of the Licensed Technology or otherwise produced by TG in connection with the Global Development Activities shall be Confidential Information of TG; (y) all Clinical Data produced by Company in connection with the Company Development Activities shall be Confidential Information of Company (except to the extent necessary for TG exercise its rights under Sections 3.7 and 11.4); and (z) any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

1.37 **"*Control*" or "*Controlled*" means (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party of the right to grant a license or sublicense to such Technology or Patent Rights as provided herein without violating the terms of any agreement or arrangement with, infringing the Patent Rights of, or misappropriating the proprietary or trade secret information of, any Third Party and without violating any Applicable Laws and (b) with respect to Proprietary Materials, the possession by a Party of the right to supply such Proprietary Materials to the other Party as provided herein without violating the terms of any agreement or arrangement with any Third Party and without violating any Applicable Laws. Notwithstanding**

the foregoing, no Party shall be deemed to Control any Technology, Proprietary Materials, or Patent Rights solely by virtue of the license grants set forth in this Agreement.

1.38 **"*Cover*" or "*Covered*" means, with respect to the Product, that the manufacture, use, sale, or other Commercialization of the Product in a particular country by an unlicensed Third Party would infringe a Valid Claim.**

1.39 **"*Defensive Action*" has the meaning set forth in Section 10.5.2(a).**

1.40 **"*Development*" or "*Develop*" means (a) all non-clinical and clinical development activities that are undertaken with respect to the Product, including, without limitation, (i) the conduct of Clinical Trials, toxicology and pharmacology testing, test method development and stability testing, formulation development, delivery system development, quality assurance and quality control development, analytical method development, human clinical studies, regulatory affairs activities, statistical analysis, and report writing; (ii) the preparation of Clinical Trial design**

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and operations; and (iii) without limiting the generality of the foregoing (i), the conduct of Post Approval Clinical Trials and any post-marketing safety surveillance and maintaining databases, including studies to support Product positioning and/or market penetration; and (b) any and all other activities that may be necessary or useful to obtain Regulatory Approval. When used as a verb, "*Developing*" means to engage in Development and "*Developed*" has a corresponding meaning.

1.41 **"*Development Plan*" means the non-binding written plan for, and estimated budget applicable to, the anticipated Company Development Activities relating to the Product, as such written plan may be amended, modified, or updated in accordance with Section 3.4. Topics that shall be covered in the plan include: (a) any Clinical Trials (including investigator-initiated clinical trials) related to the Product in the Field that Company expects to conduct in accordance with Sections 3.1.2(b) and 3.1.3 and the expected timeline for conducting such Clinical Trials; and (b) the Drug Approval Applications for the Product in the Field in the Territory, and the expected timetable for filing such Drug Approval Applications.**

1.42 **"*Development Report*" has the meaning set forth in Section 3.6.**

1.43 **"*Dispute*" has the meaning set forth in Section 14.1.**

1.44 **"*Distribution Agreement*" has the meaning set forth in Section 2.2.2.**

1.45 **"*Distributor*" means any Person that purchases Product from Company or any of Company's Affiliates or Sublicensees for purposes of resale of Product to end users in the Territory (including any wholesalers, pharmacists, or hospitals).**

1.46 **"*DP PSA*" has the meaning set forth in Article 6.**

1.47 **"*Drug Approval Application*" means, with respect to the Product in any country or region in the Territory, an application for Marketing Authorization for the Product in such country or region. For purposes of clarity, Drug Approval Application shall include, without limitation, (a) a marketing authorization application (MAA) for Europe; (b) a counterpart of an MAA in any other country or region in the Territory; and (c) and all supplements and amendments to the foregoing.**

1.48 **"*Drug Substance*" has the meaning set forth in the DS PSA.**

1.49 **"*Drug Product*" has the meaning set forth in the DP PSA.**

1.50 **"*DS PSA*" has the meaning set forth in Article 6.**

1.51 **"*DTT Residence Certificate*" has the meaning set forth in Section 8.3.6**

1.52 **"*EMA*" means the European Medicines Agency or any successor agency or authority thereto.**

1.53 **"*Excluded Application*" means (a) any application involving the determination or monitoring of (i) the presence or absence of a disease; (ii) the stage, progression, or severity of a**

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disease or (iii) the effect on a disease of a particular treatment; (b) any application involving the selection of patients for a particular treatment; and (c) any *in vitro* applications or uses.

1.54 **"*Excluded Territory*" means all of the following countries, regions, and jurisdictions: (a) United States; (b) Canada; (c) Mexico; (d) South Korea; (e) Taiwan; (f) Singapore; (g) Indonesia; (h) Malaysia; (i) Thailand; (j) Philippines; (k) Vietnam; and (l) Myanmar; in each case, including all of its territories, commonwealths, and possessions.**

1.55 **"*Excluded Territory-Specific PMCs/PMRs*" means (a) those Post-Marketing Commitments & Requirements that are identified as Excluded Territory-Specific PMCs/PMRs on Schedule 3.1.2, and (b) any other Post-Marketing Commitment & Requirement that is specific to the Excluded Territory that arises following the Effective Date.**

1.56 **"*FCPA*" has the meaning set forth in Section 12.3.6.**

1.57 **"*FDA*" means the United States Food and Drug Administration or any successor agency or authority thereto.**

1.58 **"*Field*" means solely the treatment of relapsing forms of Multiple Sclerosis in adults, which shall comprise relapsing-remitting multiple sclerosis (RRMS) and active secondary progressive multiple sclerosis (SPMS). For purpose of clarity, the definition of "*Field*" shall not include any Excluded Application.**

1.59 **"*First Commercial Sale*" means, with respect to the Product in the Field in the Territory, the first sale, transfer, or disposition for value to an end user of such Product in the Field in the Territory after Marketing Authorization for the Product has been received in the Territory; provided, that, a First Commercial Sale shall not include: (a) any sale to an Affiliate, Sublicensee, or Distributor (unless the Affiliate, Sublicensee, or Distributor is the last entity in the distribution chain of the Product), (b) any use of the Product in Clinical Trials, pre-clinical studies, or other research or development activities, or (c) the disposal or transfer of Products for a bona fide charitable purpose, including compassionate use or named patient use.**

1.60 **"*Force Majeure*" means any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder (other than payment obligations), and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty, or accident, or war, revolution, civil commotion, act of terrorism, blockage, or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand, or requirement of any government or**

of any subdivision, authority, or representative of any such government.

1.61 **"*Global Development Activities*" has the meaning set forth in Section 3.1.1.**

1.62 **"*Global PMCs/PMRs*" means (a) those Post-Marketing Commitments & Requirements that are identified as Global PMCs/PMRs on Schedule 3.1.2, and (b) any other Post-Marketing Commitment & Requirement that is required, whether by the applicable Regulatory Authorities or as a voluntary commitment by the holder of the Marketing Authorization, in connection with the maintenance of Marketing Authorizations for the Product in the Field in both the Excluded Territory and the Territory that arises following the Effective Date.**

1.63 **"*GLP*" means the then-current Good Laboratory Practice Standards or comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority.**

1.64 **"*GMP*" means current Good Manufacturing Practices that apply to the Manufacture of Drug Substance and/or the clinical or commercial supply of Products or comparable regulatory standards promoted or endorsed by the applicable Regulatory Authority and the International Conference on Harmonization Guidelines ICH Q7 Good Manufacturing Practice Guidance for API or the principles and guidelines of Good Manufacturing Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice.**

1.65 **"*Good Clinical Practice*" or "*GCP*" means the applicable regulations or guidance relating to the design, conduct, recording, and reporting of Clinical Trials that involve the participation of human subjects, when generating Clinical Trial data intended to be submitted to Regulatory Authorities, as set forth under Applicable Law and any regulations or guidance documents promulgated thereunder, including but not limited to the ICH E6 consolidated guidance on Good Clinical Practice.**

1.66 **"*GVP*" means Good Pharmacovigilance Practice or comparable regulatory standards that apply for the conduct of pharmacovigilance as endorsed by the**

applicable Regulatory Authority and guidelines as defined in Directive 2001/83/EC.

1.67 **"*Hadam License*" means that certain License Agreement, dated August 15, 2006, by and between Laboratoire Français du Fractionnement et des Biotechnologies S.A. and Dr. Martin R. Hadam, as it may be amended from time to time.**

1.68 **"*ICH*" has the meaning set forth in Section 3.5.**

1.69 **"*Indemnified Party*" has the meaning set forth in Section 13.3.**

1.70 **"*Indemnifying Party*" has the meaning set forth in Section 13.3.**

1.71 **"*Indication*" means each separate and distinct disease, illness, and/or condition, interruption, cessation, or disorder of a particular bodily function, system, tissue type, or organ, or sign or symptom of any such items or conditions, regardless of the severity, frequency, or route of any treatment, dosage strength, or patient class, for which Regulatory Approval is being sought. For clarity, for the purpose of this Agreement (i) [***], and (ii) [***].**

1.72 **"*Initial Period*" has the meaning set forth in Section 5.5.1.**

1.73 **"*Infringement*" has the meaning set forth in Section 10.5.1(a).**

1.74 **"*Infringement Notice*" has the meaning set forth in Section 10.5.1(a).**

1.75 **"*Investigator's Brochure*" means a compilation of preclinical data and Clinical Data with respect to a new investigational drug that is proposed for filing with a Regulatory Authority and used to provide information to clinical investigators and Regulatory Authorities.**

1.76 **"*JSC*" has the meaning set forth in Section 7.1.**

1.77 **"*Key Markets*" means [***].**

1.78 **"*Key Multiple Sclerosis Centers*" means the approx. [***] centers dedicated to the treatment of Multiple Sclerosis in the Territory that are referred to in Section 2.3 of the initial Commercialization Plan attached hereto as Exhibit B and the details of which Company will**

provide to TG without undue delay following the Effective Date.

1.79 **"*Knowledge*" means, with respect to a Party, the actual knowledge of any executive officer (as defined for purposes of Section 14 of the Securities Exchange Act of 1934, as amended) of such Party.**

1.80 **"*LFB*" means, collectively, GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S., and LFB/GTC LLC.**

1.81 **"*LFB Background Patent Rights*" means the Patents Controlled by TG pursuant to the LFB License that are identified therein as "Background Patent Rights," including, as of the Effective Date, as listed in Schedule 12.2.2(a).**

1.82 **"*LFB License*" means that certain Exclusive License Agreement, dated January 30, 2012, by and among GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S., LFB/GTC LLC, and TG Biologics, Inc. (f/k/a TG Therapeutics, Inc.), as amended from time to time.**

1.83 **"*Licensed Patent Rights*" means any Patent Right (including any Product Improvement solely to the extent Company exercises its option in Section 3.2.1(c)) that (a) is necessary or useful for Company to Commercialize the Product in the Field (including any New CNS Indication solely to the extent Company exercises its option in accordance with Section 3.2.1(d)) in the Territory, and (b) is (i) Controlled by TG as of the Effective Date, or (ii) developed or reduced to practice, and Controlled, by TG under and pursuant to this Agreement after the Effective Date. For clarity, the Licensed Patent Rights, including, as of the Effective Date, as listed in Schedule 12.2.2(b), include, without limitation, such Patents Rights Controlled by TG pursuant to the LFB License, but exclude the LFB Background Patent Rights.**

1.84 **"*Licensed Technology*" means any Technology (including any Product Improvement solely to the extent Company exercises its option in Section 3.2.1(c)) that (a) is necessary or useful for Company to Commercialize the Product in the Field (including any New CNS Indication solely to the extent Company exercises its option in accordance with Section 3.2.1(d)) in the Territory, and (b) is (i) Controlled by TG as of the Effective Date or (ii) developed or reduced to practice, and Controlled, by TG under and pursuant to this Agreement after the Effective Date. For clarity, the Licensed Technology (A) includes, without limitation, such Technology that is Controlled by TG pursuant to the LFB License, and (B) [***]) (the "*Excluded Manufacturing Know-How*").**

1.85 **"*Licensed Trademark*" means BRIUMVI (or, solely to the extent that BRIUMVI is not available for use**

or registration in a particular country in the Territory or otherwise as mutually agreed by the Parties, any other trademark chosen in the future by TG and Company collaboratively, for Commercialization purposes), together with all goodwill associated therewith, including, without limitation, EUTM Reg. No. 018489086 and all other BRIUMVI trademarks applied for and/or registered in any country in the Territory. A list of those Licensed Trademarks

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applied for and/or registered at the Effective Date is attached hereto in Schedule 12.2.2(c). For the avoidance of doubt, any BRIUMVI (or alternatively chosen trademarks) applied for and registered in the future shall automatically be included in Schedule 12.2.2(c) and shall become part of the licensing regime under this Agreement.

1.86 **"*Losses*" has the meaning set forth in Section 13.1.**

1.87 **"*Manufacture*" or "*Manufacturing*" or "*Manufactured*" means all activities related to the production of any Drug Substance or Drug Product, including the manufacture, receipt, inspection, storage, and handling of materials, and the manufacture, processing, purification, packaging, labeling, warehousing, quality control testing (including in-process release and stability testing), shipping, and release of Drug Substance or Drug Product.**

1.88 **"*Marketing Authorization*" means, with respect to the Product in any country or region in the Territory, the Regulatory Approval required by Applicable Laws to market and sell the Product for use in the Field in such country or region. For purposes of clarity, "*Marketing Authorization*" in the European Union means marketing authorization for the Product granted by the EMA pursuant to Council Directive 2001/83/EC, as amended, or Regulation (EC) No 726/2004, as amended. For the avoidance of doubt, Marketing Authorization does not include Pricing Approvals and Reimbursement Approvals.**

1.89 **"*Milestone Payments*" has the meaning set forth in Section 8.2.1.**

1.90 **"*Net Sales*" means the gross amount billed or invoiced by Company or any of its Affiliates, Sublicensees, or Distributors (each, a "*Seller*") to Third Parties in the Territory for sales or other dispositions or transfers for**

value of the Product, *less* (a) allowances for trade, quantity, and cash discounts actually allowed and taken; (b) freight, transportation, insurance, postage charges, and customs duties included on a Seller's bill or invoice or as a separate item; (c) credits, rebates, allowances, and amounts repaid due to returns, recalls, or government regulations, including allowances for uncollectible amounts and/or bad debts on previously sold Products; (d) retroactive price reductions that are actually allowed or granted; (e) sales taxes, excise taxes, value-added taxes, and other taxes (other than income taxes) levied on the invoiced amount; and (f) duties, tariffs, and other governmental charges. In addition, Net Sales are subject to the following:

(i) **Net Sales shall not include sales or transfers between Company and any of its Affiliates, Sublicensees, or Distributors unless such Affiliate, Sublicensee, or Distributor is the end user of the Product.**

(ii) **If any Seller effects a sale, disposition, or transfer of the Product to a Third Party in a particular country other than on customary commercial terms or for non-monetary consideration, the Net Sales of such Product to such Third Party shall be deemed to be "the fair market value" of such Product. For purposes of this subsection (ii), "fair market value" means the value that would have been derived had such Product been sold as a separate product to another customer in the country concerned on customary commercial terms.**

(iii) **For purposes of this Agreement, "sale" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of**

Product at no charge for academic research, preclinical, clinical, or regulatory purposes (including the use of the Product in Clinical Trials) or in connection with patient assistance programs or other charitable purposes or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry and/or which is reasonably proportional to the market for the Product).

1.91 **"*New CNS Indication*" has the meaning set forth in Section 3.2.1(d).**

1.92 **"*New CNS Indication Development Activities*" has the meaning set forth in Section 3.2.1(d).**

1.93 **"*New CNS Indication IP*" has the meaning set forth in Section 3.2.1(d).**

1.94 **"*New CNS Indication Notice*" has the meaning set forth in Section 3.2.1(d).**

1.95 **"*New Commercialization Provider*" means the provider of Commercialization activities and/or Company Development Activities (or activities which are substantially the same as, or the replacements to, the Commercialization activities and/or the Company Development Activities) as a successor to Company following the termination of all or part of this Agreement.**

1.96 **"*New Sales Representative*" has the meaning set forth in Section 5.3.2(c).**

1.97 **"*Officials*" has the meaning set forth in Section 12.3.6.**

1.98 **"*Optional Territory-Based Development Activities*" has the meaning set forth in Section 3.1.3.**

1.99 **"*Patent Rights*" means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention, and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations, and extensions thereof, and all foreign counterparts of any of the foregoing.**

1.100 **"*Payment*" has the meaning set forth in Section 12.3.6.**

1.101 **"*Person*" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, or similar entity or organization, including a government or political subdivision, department, or agency of a government.**

1.102 **"*Phase 1 Clinical Trial*" means a human clinical trial conducted for the Product in any country that would satisfy the requirements of 21 CFR 312.21(a), as amended (or its foreign equivalent, e.g., Regulation (EU) No 536/2014).**

1.103 **"*Phase 2 Clinical Trial*" means a human clinical trial conducted for the Product for any Indication that would satisfy the requirements of 21 CFR 312.21(b), as**

amended (or its foreign equivalent, e.g., Regulation (EU) No 536/2014) and is intended to explore one or more

doses, dose response, and duration of effect, and to generate initial evidence of clinical activity and safety for the Product in the target patient population.

1.104 **"*Phase 3 Clinical Trial*" means a pivotal human clinical trial conducted for the Product for any Indication that would satisfy the requirements of 21 CFR 312.21(c), as amended (or its foreign equivalent, e.g., Regulation (EU) No 536/2014) and is intended to confirm with statistical significance the efficacy and safety of the Product with respect to a particular Indication, and is performed to obtain Marketing Authorization.**

1.105 **"*Pivotal Clinical Trial*" means (a) a Phase 3 Clinical Trial or, (b) a Phase 2 Clinical Trial to the extent: (i) in the United States, the protocol for that Phase 2 Clinical Trial shall have been reviewed by the FDA under its current Special Protocol Assessment Guidelines (or equivalent guidelines issued in the future), and any comments from the FDA on that protocol are incorporated in the final protocol for that Phase 2 Clinical Trial or are resolved to the FDA's satisfaction as evidenced by further written communications from the FDA; or (ii) a process with a comparable result – acceptance of a Phase 2 Clinical Trial protocol as "potentially pivotal" – has occurred with the EMA/CHMP in the European Union; or (iii) based on the results of that Phase 2 Clinical Trial, either the FDA or the EMA has determined that the Phase 2 Clinical Trial can be considered as a pivotal clinical trial for purposes of obtaining Marketing Authorization; or (iv) the equivalent of the foregoing in other jurisdictions in the Territory.**

1.106 **"*Post Approval Clinical Trials*" means any Phase 4 clinical trial and/or any clinical trial undertaken after any Marketing Approval is granted for the Product in the Field in the Territory, such as, without limitation, an Investigator sponsored study.**

1.107 **"*Post-Marketing Commitments & Requirements*" has the meaning set forth in Section 3.1.2.**

1.108 **"*Pricing*" means the determination of Product pricing at all levels, including the Product list price (also referred to as Wholesale Acquisition Cost) and the net price in which the Product is offered to purchasers and**

payers (including both private sector and government entities).

1.109 "*Pricing Approval*" means any pricing approvals, guidance, or recommendations reasonably necessary to market the Product in the Field in the Territory.

1.110 "*Prior Year Spend*" has the meaning set forth in Section 7.3.

1.111 "*Product*" means Briumvi, 150mg of the Compound at a concentration of 25 mg/mL for solution for intravenous infusion in the Field.

1.112 "*Product Improvement*" means any development, innovation, and/or modification to the Product in the Field that (a) may modify the Product Label, or (b) otherwise relates to chemistry, manufacturing, and controls (CMC) of the Product in the Field (including, for the avoidance of doubt and without limitation, changes to and modifications of the Manufacturing process and the supply chain, consistent with the types of activities specified on Exhibit D attached hereto). For clarity, (y) the development of a pharmaceutical product to be used inside the Field containing the Compound as active ingredient and using a route of administration other than intravenous infusion (an "*MoA Product Improvement*") and (z) the establishment of any

alternative sources for manufacturing the Product (drug substance and/or drug product) shall, in each case (y) and (z), be considered a Product Improvement. Notwithstanding the foregoing, the term Product Improvement does not include any development, innovation and/or modification that (i) results in a ROFN Product or a New CNS Indication for the Product, or (ii) results from any Territory-Specific CMC PMCs.

1.113 "*Product Improvement Development Activities*" has the meaning set forth in Section 3.2.1(c).

1.114 "*Product Improvement Notice*" has the meaning set forth in Section 3.2.1(c).

1.115 "*Product Label*" means (a) with respect to the European Economic Area countries, the label for the Product in the Field that received initial authorization by the EMA on 30 March 2023 (EMA/H/C/005914), and (b) with

respect to all other countries and/or regions in the Territory, the label for the Product in the Field in such countries and/or territories, which is substantially similar to the label described in subsection (a) with respect to all material characteristics.

1.116 **"*Promotional Materials*" has the meaning set forth in Section 2.1.3(d).**

1.117 **"*Proprietary Materials*" means any tangible chemical, biological, or physical materials that (a) are furnished by or on behalf of one Party to the other Party in connection with this Agreement, whether or not specifically designated as proprietary by such Transferring Party, or (b) that are otherwise conceived or reduced to practice by Company in the conduct of the Company Development Activities and/or in connection with the Commercialization of the Product.**

1.118 **"*Qualified Person*" has the meaning assigned to such term in Article 48 of Directive 2001/83/EC, as amended, and Article 52 of Directive 2001/82/EC.**

1.119 **"*Raw Material*" has the meaning set forth in the Supply Agreement.**

1.120 **"*Recall*" has the meaning set forth in Section 5.8.**

1.121 **"*Regulatory Approval*" means, with respect to the Territory, any approval, product and establishment license, registration, or authorization of any Regulatory Authority required for the Manufacture, use, storage, importation, exportation, transport, or distribution of the Product in the Territory, including any Marketing Authorization, Reimbursement Approval, and Pricing Approval.**

1.122 **"*Regulatory Authority*" means any national, international, regional, state, or local regulatory agency, department, bureau, commission, council, or other governmental entity with authority over the distribution, importation, exportation, Manufacture, production, use, storage, transport, clinical testing, marketing, Pricing, or sale of the Product in the Field in the Territory, including, without limitation, the EMA and The Medicines and Healthcare Regulatory Authority of the United Kingdom.**

1.123 **"*Regulatory Filings*" means, collectively: (a) all MAAs, establishment license applications, Drug Master Files, and all other similar filings (including, without limitation, counterparts of any of the foregoing in any country in the Territory); (b) all supplements and amendments to any of the foregoing; (c) all data and other information contained in, and correspondence relating to, any of the foregoing; and (d) any and all orphan drug applications.**

1.124 **"*Reimbursement Approval*" means any pricing reimbursement registration or listing on formularies or any other similar approvals necessary or useful to an optimal introduction of the Product in the Field on the market.**

1.125 **"*Results*" has the meaning set forth in Section 9.4.**

1.126 **"*ROFN Opportunity*" has the meaning set forth in Section 2.5.**

1.127 **"*ROFN Product*" means any pharmaceutical product that (a) contains the Compound as an active ingredient, and (b) is for an indication that is both: (i) outside the Field and (ii) not a New CNS Indication.**

1.128 **"*Sales Target*" means, [***].**

1.129 **"*SBL*" has the meaning set forth in the Supply Agreement.**

1.130 **"*Serious Adverse Event*" means any untoward medical occurrence that, at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect, including as more fully defined in 21 CFR § 312.32 and Art. 1 para. 12 of Directive 2001/83/EC.**

1.131 **"*Significant Development Event*" means any of the following material Development events, a summary of which shall be included in any Development Report: (a) any material interaction and/or written correspondence between Company and any Regulatory Authority with respect to the Product; (b) any material event with respect to any Clinical Trial involving the Product conducted by or on behalf of Company, including any such event that is ongoing as of the date of the applicable Development Report, or is reasonably expected to occur or be initiated within [***] ([***]) [***] of the date of the applicable Development Report; and (c) any material result obtained in the conduct of any Clinical Trial involving the Product conducted by or on behalf of Company during the period covered by the Development**

Report. For purposes of clarity, all information provided to TG with respect to Significant Development Events, shall be deemed to be Confidential Information of Company. For purposes of this definition, "material" shall be defined as any event and/or result which have had or may have a significant impact on the activities and timelines defined in the Development Plan of the Product.

1.132 **"*Sublicensee*" means any Third Party to which Company grants a sublicense in accordance with Section 2.2.**

1.133 **"*Sublicense Agreement*" means any agreement by and between a Party and a Sublicensee which is entered into in accordance with Section 2.2.**

1.134 **"*Supply Agreement*" has the meaning set forth in Section 6.1.**

1.135 **"*Taxes*" means: (a) any form of tax on income, profits and gains; and (b) all other taxes, levies, duties, imposts, charges, contributions and withholdings in the nature of taxation imposed, collected or assessed by, or payable to, a Tax authority, including any excise, property, value added, sales, transfer, franchise and payroll taxes, in each case regardless of whether levied as a primary, secondary or joint liability and together with all penalties, fines, charges, additions to tax and interest relating to any of the foregoing or to any late or incorrect return in respect of any of them.**

1.136 **"*Technology*" means, collectively, all inventions, discoveries, improvements, trade secrets, and proprietary information and methods, whether or not patentable or patented, including without limitation: (a) methods of use of, and structural and functional information pertaining to, chemical compounds; (b) compositions of matter, data, formulations, processes, techniques, know-how, and results (including any negative results); and (c) results of clinical trials, pre-clinical trials, and other Development activities, including, without limitation, Clinical Data.**

1.137 **"*Term*" has the meaning set forth in Section 11.1.**

1.138 **"*Territory*" means worldwide, other than the Excluded Territory.**

1.139 **"*Territory-Specific CMC PMCs*" means any Post-Marketing Commitment & Requirement that is related to CMC of the Product in the Field that is specific to the Territory (and, for clarity, not the Excluded Territory) and that arises prior to or following the Effective Date.**

1.140 **"*Territory-Specific Requirements*" means (a) the Post-Marketing Commitment & Requirements that are identified as a Territory-Specific Requirement on Schedule 3.1.2, (b) any other Post-Marketing Commitment & Requirement that is specific to the Territory, not related to CMC, and arises following the Effective Date, and (c) any Development studies or activities that are specific to the Territory, arise following the Effective Date, and are required to obtain Marketing Authorization for the Product in the Field in a country in the Territory, but not including Territory-Specific CMC PMCs.**

1.141 **"*TG EU Commercial Personnel*" means EU-based marketing, medical and/or sales personnel engaged by TG from time to time, at TG's sole expense, to perform specific targeted interactions with key opinion leaders regarding Multiple Sclerosis located in the Territory and/or to perform market assessment, in each case as directed by TG and subject to prior discussion and agreement by the JSC, to support the commercial success of the Product in the Field in the European Economic Area.**

1.142 **"*TG Indemnities*" has the meaning set forth in Section 13.1.**

1.143 **"*TG Residence Confirmation*" has the meaning set forth in Section 8.3.6.**

1.144 **"*Third Party*" means (a) with respect to Company, any Person other than Company and its respective Affiliates, Sublicensees, and Distributors and (b) with respect to TG, any Person other than its Affiliates.**

1.145 **"*Transfer Claimant*" has the meaning set forth in Section 11.4.4(i).**

1.146 **"*Transfer Regulations*" means the Transfer of Undertakings (Protection of Employment) Regulations 2006, as amended, augmented, and/or replaced by similar law enacted by the UK Government from time-to-time, the EU Directive 2001/23/EC on the approximation of the laws of the European Union member states relating to the**

safeguarding of employees rights in the event of transfers of undertakings or businesses (referred to as the Acquired Rights Directive), and any national laws implementing the same or similar law(s) or any successor legislation in force from time to time; and any other law (as amended, augmented and/or replaced by similar law(s) from time-to-time) which governs or provides for the automatic transfer of any employee.

1.147 **"*Transferring Employees*" has the meaning set forth in Schedule 11.2.5(a)(v).**

1.148 **"*Upfront Payment*" has the meaning set forth in Section 8.1.**

1.149 **"*Valid Claim*" means any claim of (a) an issued unexpired patent that (i) has not been finally canceled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (ii) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (iii) has not been rendered unenforceable through terminal disclaimer or otherwise, and (iv) is not lost through an interference proceeding that is unappealable or unappealed within the time allowed for appeal; or (b) a claim of a pending Patent application, which claim has not been abandoned or finally disallowed without the possibility of appeal.**

2. COMMERCIAL LICENSE GRANTS; EXCLUSIVITY

2.1 Commercial License.

2.1.1 Grant of Commercial License to Company.

(a)Subject to the terms and conditions of this Agreement, TG hereby grants to Company an exclusive (including with respect to TG and its Affiliates, except to perform its obligations and/or exercise its rights under this Agreement), royalty-bearing license or sublicense (with respect to Licensed Technology and/or Licensed Patent Rights licensed by Third Parties to TG, including, without limitation, pursuant to the LFB License), including the right to grant sublicenses as provided in Section 2.2, under the Licensed Technology and Licensed Patent Rights to sell, offer to sell, import, have imported, market, carry out the tasks assigned to Company pursuant to the Supply Agreement, and otherwise Commercialize the Product in the Field in the Territory, and, solely as set forth in Sections 3.1.2(b) and 3.1.3, to Develop the Product in the Field.

(b)Subject to the terms and conditions of this Agreement, TG hereby grants to Company a non-exclusive sublicense, including the right to grant sublicenses as provided in Section 2.2, under the LFB Background Patent Rights to the extent necessary to sell, offer to sell, import, have imported, market, carry out the tasks assigned to Company pursuant to the Supply Agreement, and otherwise Commercialize the Product in the Field in the Territory, and, solely as set forth in Sections 3.1.2(b) and 3.1.3, to Develop the Product in the Field.

2.1.2 **Reversion. Should Company, its Affiliates or its Sublicensee(s) stop the Commercialization of the Product in the Field in the Territory, any and all licenses and sublicenses granted to Company by TG in respect of the Product shall automatically revert back to TG (including licenses granted according to Sections 2.1.1 and 2.1.3). In such case, Company commits to grant to TG an exclusive, royalty-free license or sublicense (with respect to Patent Rights and other intellectual property rights licensed by Third Parties to Company), including the right to grant sublicenses through multiple tiers, under the Patent Rights and other Technology and intellectual property rights Controlled by Company necessary or useful for TG to Develop, use, have used, Manufacture, have Manufactured, supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize the Product in the Field in the Territory.**

For the avoidance of doubt, the Commercialization of the Product in the Field in the Territory shall be considered as stopped if, after all Regulatory Approvals and Reimbursement Approvals have been granted in any one or more of the Key Markets:

- **the aggregate amount spent by Company or its Sublicensee(s) (or its or their Affiliates) on the Commercialization activities for the Product in the Field in the Territory is less than $[***] per [***]; or**
- **Company and/or its Sublicensee (and/or its or their Affiliates) has failed to achieve a minimum of [***] ([***]) of the Sales Target on a continuous basis for at least [***] ([***]) [***] in the Territory;**

provided, however, that the Commercialization of the Product in the Field in the Territory shall not be considered stopped if the aggregate amount spent on Commercialization activities and/or achievement of the Sales Target was not reached due to Product supply failures not attributable to Company (provided that Company has satisfied its safety stock obligations set forth in the Supply Agreement and has exhausted its safety stock of the Product).

In the event that TG exercises its rights under this Section 2.1.2, this Agreement shall terminate immediately, and, for the avoidance of doubt, Section 11.4 shall apply.

2.1.3 **Grant of License to Licensed Trademark.**

(a)Grant of License. Subject to the terms and conditions of this Agreement, TG hereby grants to Company an exclusive, royalty-bearing license to use the Licensed Trademark solely for Commercializing the Product in the Field in the Territory.

(b)Covenants of Company. Company hereby agrees that it shall use the Licensed Trademark as the primary brand of the Product in the Field in the Territory, and that all use of the Licensed Trademark by Company, and any goodwill associated with the use of the Licensed Trademark by Company, shall inure to the benefit of TG. Company hereby agrees that nothing in this Agreement shall give Company any right, title, or interest in the Licensed Trademark other than the right to use the Licensed Trademark in accordance with this Agreement. Company further agrees that it will not: (i) oppose or assist any Third Party in opposing any application for registration, re-registration, or renewal of the Licensed Trademark; (ii) apply for or otherwise seek (or assist any Third Party in applying for or otherwise seeking) complete or partial revocation, cancellation, invalidation, or removal of the Licensed Trademark from any register, or

(iii) challenge or bring (or assist any Third Party in challenging or bringing) any proceeding or action in relation to the use or ownership of the Licensed Trademark.

(c)Prosecution, Enforcement, and Defense of Licensed Trademark. TG shall have the first right (but not obligation) to apply for registration of, prosecute, enforce, and defend the Licensed Trademark in

the Territory, at TG's sole expense and discretion. Company agrees that it will not apply for the registration of the Licensed Trademark (or any mark confusingly similar thereto) anywhere in the world; provided, however, that in the event TG waives its first right to take any such prosecution, enforcement, or defense action, TG shall deliver to Company written notice of such waiver, and, solely with respect to the action specified in such waiver, Company shall have the right to take such actions, in TG's name, and shall (i) be solely responsible for all expenses incurred in connection therewith and (ii) receive all proceeds that result from any such enforcement or defense action specified in the respective waiver, provided that Company shall keep TG reasonably informed with respect to all such actions and incorporate in good faith all of TG's comments in connection therewith.

(d)Use of Licensed Trademark. Company shall use the Licensed Trademark solely (i) in the manner specified in this Agreement and (ii) in connection with the Product in the Field in the Territory, and not for any other goods or services. Additionally, Company (iii) shall ensure, to the extent legally permissible under Applicable Law, that use of the Licensed Trademark is accompanied by an acknowledgement that the Licensed Trademark is owned by TG, (iv) shall comply strictly with trademark style and usage standards provided by TG in connection with use of the Licensed Trademark within [***] ([***]) [***] of the Effective Date, such standards to be market-standard, not containing onerous provisions (the "*Brand Guidelines*"), which shall, at such time, be attached hereto as Exhibit F, (v) shall not use the Licensed Trademark in a way that is reasonably likely to materially prejudice its distinctiveness or validity or the goodwill of TG therein, (vi) shall use the Licensed Trademark with the trademark registration symbol ® or ™, as appropriate, and (vii) shall not use any trademarks or trade names so resembling the Licensed Trademark as to be likely to cause confusion or deception. Company agrees not to use any other trademark or service mark in combination with the Licensed Trademark without the prior written consent of TG. Company, at its sole cost and expense, will provide to TG representative samples of all products, product packaging, literature, brochures, signs, and advertising materials (collectively, "*Promotional Materials*") prepared by Company that bear, display, or include any reference to the Licensed Trademark or that otherwise promote the Product, and Company shall obtain the written approval of TG with respect to all such Promotional Materials prior to the first use thereof, such approval (or rejection or other comments) to be provided by TG within ten (10) Business Days of receiving such samples; provided, however, that Company acknowledges and agrees that it shall be responsible for ensuring, and shall ensure, compliance of

the Promotional Materials with Applicable Laws and Marketing Authorizations and consistency with Promotional Materials used by TG in the Excluded Territory and made available by TG to Company. For clarity, Company assumes no liability for TG's use of Promotional Material in the Excluded Territory. Company shall store and archive the Promotional Materials in accordance with Applicable Laws. Company will not distribute or otherwise use any samples or materials or other media bearing or displaying the Licensed Trademark unless and until TG has notified Company in writing of TG's approval, which approval shall not be reasonably withheld. Upon TG's request, Company shall grant TG the right to use any Promotional Materials developed

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by Company hereunder in connection with Commercialization of the Product in the Excluded Territory and/or outside the Field in the Territory, as applicable.

(e)Notice. Company shall promptly notify TG (i) of any claim, threat, lawsuit, filing, or other notice or allegation of infringement of which it is aware regarding Company's use of the Licensed Trademark and/or (ii) if it becomes aware of the existence of any Third Party applications to register anywhere in the world any mark or name that consists of or incorporates the Licensed Trademark. TG shall have the sole right, but not the obligation, to bring infringement, unfair competition, or other claims or proceedings involving the Licensed Trademark, and Company hereby acknowledges and agrees that it shall have no such right. If requested by TG, Company shall cooperate with TG in connection with any such action, at Company's reasonable cost; provided, however, that to the extent that such cooperation is likely to require material and significant expenditure of resources, then the Parties shall discuss and agree in good faith the manner in which Company may reasonably support TG in connection therewith and reasonable compensation to Company by TG in light of any material expenditures.

2.2 **Right to Sublicense.**

2.2.1 **Sublicense. Company shall have the right to grant sublicenses under the licenses granted to it under Section 2.1.1 to any Sublicensee, with [***] ([***]) [***] prior written notification to TG; provided that (a) the**

terms of each such Sublicense Agreement shall be consistent with the rights and obligations of the Parties under this Agreement and the terms of this Agreement (including, without limitation and for the avoidance of doubt, Sections 2.4, 5.3, 9, and 10); (b) it shall be a condition of any such Sublicense Agreement that each such Sublicensee agrees to be bound by the terms of this Agreement applicable to the Development and Commercialization of the Product in the Field in the Territory; (c) Company shall provide TG with a complete and accurate copy of any such Sublicense Agreement within [***] ([***]) [***] of the execution of each such Sublicense Agreement; and (d) Company shall not be relieved of its obligations pursuant to this Agreement as a result of such Sublicense Agreement, except to the extent such obligations are satisfactorily performed by any such Sublicensee. TG shall be named a third-party beneficiary to any Sublicense Agreement. Without limiting the generality of the foregoing, in the event that any Sublicensee breaches any of the provisions of this Agreement, including, without limitation, confidentiality, non-compete, intellectual property, and/or diligence obligations, then TG shall have the right to cause Company to terminate such Sublicense Agreement, in addition to any other rights or remedies available at law or in equity. For the avoidance of doubt, Company shall be liable for the acts and omissions of any Sublicensee, as if they were its own.

2.2.2 **Grant of Rights to Distributors. Company or any of its Affiliates and Sublicensees shall have the right, with [***] ([***]) [***] prior written notification to TG, to appoint one or more Distributors for the Product in the Field in the Territory; provided that (a) the terms of any such agreement with a Distributor (each, a "*Distribution Agreement*") shall be consistent with the rights and obligations of the Parties under this Agreement and the terms of this Agreement (including, without limitation and for the avoidance of doubt, Sections 2.4, 5.3, 9, and 10); (b) it shall be a condition of any such Distribution Agreement that each such Distributor agrees to be bound by the terms of this Agreement applicable to the Commercialization of the Product in the Field in the Territory; (c) Company shall provide TG with a complete and accurate copy of any**

such Distribution Agreement within [***] ([***]) [***] of the execution of each such Distribution Agreement; and (d) Company shall not be relieved of its obligations pursuant to this Agreement as a result of such Distribution Agreement, except to the extent such obligations are satisfactorily performed by any such Distributor. TG shall be named a third-party beneficiary to any Distribution Agreement. Without limiting the generality of the foregoing, in the event that any Distributor breaches any of the provisions of this Agreement, including, without limitation, confidentiality, non-compete, intellectual property, and/or diligence obligations, then TG shall have the right to cause Company to terminate such Distribution Agreement, in addition to any other rights or remedies available at law or in equity. Company shall be liable for the acts and omissions of any Distributor, as if they were its own.

2.3 **No Other Rights. Company shall have no rights to use or otherwise exploit Licensed Technology, Licensed Patent Rights, LFB Background Patent Rights, TG Proprietary Materials, or the Licensed Trademark, except as expressly set forth in this Agreement. Any rights of TG not expressly granted to Company under the provisions of this Agreement will be retained by TG. Nothing in this Agreement shall be construed to confer any rights upon Company by implication, estoppel, or otherwise as to any intellectual property of TG, other than the rights under the Licensed Technology, Licensed Patent Rights, LFB Background Patent Rights, and Licensed Trademark expressly granted herein. All rights, titles, and interests not specifically and expressly granted by TG hereunder are hereby reserved. Without limiting the generality of the foregoing, Company shall have no right to use any of the Licensed Technology, Licensed Patent Rights, LFB Background Patent Rights, TG Proprietary Materials, the Compound, and/or the Product to develop any product independent of the explicit rights and obligations set forth in this Agreement, including, without limitation, to reverse engineer the Product.**

2.4 **Non-Compete.**

2.4.1 **To the maximum extent permissible under Applicable Law, from the Effective Date until Company ceases any and all Company Development Activities (with no intent to conduct any additional Company Development Activities), Company shall not, and shall cause each of its Affiliates to not, (a) conduct any activity, either on its own or with, for the benefit of, or sponsored by, any Third Party, that, in any case, involves the research and/or Development of any other anti-CD 20 monoclonal antibody, or any compound that embodies or is derived from any anti-CD 20 monoclonal antibody, or any biosimilar of the Product, for use in the Field,**

including, without limitation, by way of internal development, licensing, and/or acquisition, and/or (b) otherwise conduct or be engaged in Development activities with respect to a Competitive Program.

2.4.2 **To the maximum extent permissible under Applicable Law, from the First Commercial Sale of the Product in the Field in the Territory until the expiration or termination of this Agreement, Company shall not, and shall cause each of its Affiliates to not, (a) conduct any activity, either on its own or with, for the benefit of, or sponsored by, any Third Party, that, in any case, involves the Commercialization of any other anti-CD 20 monoclonal antibody, or any compound that embodies or is derived from any anti-CD 20 monoclonal antibody, or any biosimilar of the Product, for use in the Field in the Territory, including, without limitation, by way of licensing and/or acquisition, or (b) otherwise conduct or be engaged in Commercialization activities with respect to a Competitive Program in the Territory.**

2.5 **[***]. [***].**

2.6 **TG Change of Control. In the event that TG undergoes a Change of Control, the Parties acknowledge and agree that, for the avoidance of doubt, any Patent Rights, Technology, and other intellectual property rights Controlled by any such Third Party acquirer and/or its Affiliates shall be specifically excluded from the definitions of Licensed Patents Rights and Licensed Technology.**

2.7 **Acknowledgement of LFB License and Covenants of TG.**

2.7.1 **Notwithstanding any provision to the contrary set forth in this Agreement, the Parties acknowledge that the rights and licenses granted to Company hereunder are subject to TG's rights and license under the LFB License, and nothing in this Agreement will be construed to grant to Company any rights beyond those that TG has the right to grant to Company pursuant to the LFB License. Company acknowledges and agrees that, in accordance with Section 2.2.1 of the LFB License, it shall be bound by the terms of the LFB License applicable to the Development and Commercialization of the Product in the Field in the Territory.**

2.7.2 **TG covenants to Company during the Term to comply, in all material respects, with the LFB License. Without limiting the generality of the foregoing, TG shall not take any action or omit to take any action that would cause TG to be in material breach of the LFB License or give rise to a right by LFB to terminate the LFB License wholly or partly.**

2.7.3 **In the event that (a) the LFB License is terminated, (b) this Agreement is in effect at the time of such termination, and (c) Company is not in material breach of this Agreement, then, upon the written election of Company, the sublicense granted in Section 2.1 with respect to rights sublicensed pursuant to the LFB License will (x) survive such termination of the LFB License, and (y) at LFB's election, either (i) this Agreement shall be immediately and automatically assigned by TG to LFB effective immediately prior to such termination and deemed to be a direct license from LFB to Company solely with respect to such rights sublicensed pursuant to the LFB License, or (ii) Company shall be deemed to be a direct licensee of LFB, subject to the terms of the LFB License, provided that the license grant from LFB to Company shall be solely with respect to such rights sublicensed hereunder pursuant to the LFB License.**

2.7.4 **TG shall not, without Company's prior written consent, (a) amend the LFB License in any manner that adversely affects Company's rights and obligations under this Agreement; and/or (b) assign the LFB License, only if and to the extent such assignment is related to the rights granted under Section 2.1, to any Third Party or any TG Affiliate, except no consent shall be required in the event that: (x) this Agreement is also assigned to such same Third Party (for the avoidance of doubt, in accordance with Section 14.11) or TG Affiliate, and/or (y) for the avoidance of doubt, TG assigns, makes a collateral assignment of, and/or otherwise encumbers the LFB License in connection with any Third Party financing transaction of TG and/or its Affiliates.**

3. DEVELOPMENT

For the sake of clarity, in this Article 3, Company means Company, and where applicable, its Affiliates, Sublicensees, and Distributors.

3.1 **Development.**

3.1.1 **Responsibility for Development Generally**. **TG shall have the sole right to conduct, and shall have full control and authority over, the Development of the Product in the Field, whether in the Territory or the Excluded Territory, other than the Company Development Activities (the "*Global Development Activities*"). For clarity, nothing herein shall be construed to limit TG's rights with respect to the Development of the Compound and/or Product outside the Field (whether in the Territory or the Excluded Territory) or for any purpose in the Excluded Territory.**

3.1.2 **Regulatory Authority Required Development Activities**. **The Parties acknowledge and agree that, both in the Territory and the Excluded Territory, certain additional Development activity is or will be required, whether by the applicable regulatory authorities or as a voluntary commitment by the holder of the marketing authorization, to be conducted following the granting of a marketing authorization for the Product in the Field to maintain such marketing authorization (the "*Post-Marketing Commitments & Requirements*"). To TG's Knowledge, Schedule 3.1.2 sets forth a complete and accurate list of the Post-Marketing Commitments & Requirements as of the Effective Date. Responsibility for the conduct of such Post-Marketing Commitments & Requirements and certain other Development activities relating to the Product in the Field in the Territory shall be as follows:**

(a)TG's Responsibilities. With respect to any Post-Marketing Commitments & Requirements that are (i) Excluded Territory-Specific PMCs/PMRs, (ii) Global PMCs/PMRs, and/or (iii) Territory-Specific CMC PMCs, TG shall have the sole right to conduct, and shall have full control and authority, over all such Post-Marketing Commitments & Requirements.

(b)Company's Responsibilities. Except as set forth in Schedule 3.1.2, Company shall have the sole right and responsibility for, and shall, subject to the provisions of Sections 7.2 and 7.3, have full control and authority over the Territory-Specific Requirements.

3.1.3 **Company Optional Development Activities**. **In the event that Company desires to conduct any Development activities with respect to the Product in the Field in the Territory, other than the Territory-Specific Requirements ("*Optional Territory-Based Development Activities*" and, collectively with the Territory-Specific Requirements, the "*Company Development Activities*"), Company shall submit a written request to TG through the JSC, which such request shall describe, in reasonable detail, the desired Optional Territory-Based Development Activities, proposed timeline, and rationale for such**

activities. TG shall, within [***] ([***]) [***] of delivery of such notice, respond to Company approving or rejecting such request or otherwise requesting additional information or discussion, TG's consent not unreasonably to be withheld; provided, however, that, without limiting the generality of the foregoing and for the avoidance of doubt, TG shall have the right to withhold its consent if, in its reasonable discretion, it determines that any such proposed Optional Territory-Based Development Activity creates a material health or safety risk with respect to the Product or may have a material negative effect on the Commercialization of the Product (whether in the Territory, the Excluded Territory, or both).

3.2 **Development Costs and Payments.**

3.2.1 **Global Development Activities. TG shall perform the Global Development Activities at its cost, except as follows:**

(a)Territory-Specific CMC PMCs. TG shall invoice Company, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by TG in connection with the performance of any Territory-Specific CMC PMCs.

(b)Global PMCs/PMRs. With respect to any Global PMCs/PMRs, TG shall invoice Company, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by TG following the Effective Date in connection with the performance of the Global PMCs/PMRs indicated in the budget for such Global PMCs/PMRs according to Schedule 3.2.1(b), and any costs exceeding the budget indicated in Schedule 3.2.1(b) and not pre-agreed in writing by the Company (such consent not to be unreasonably withheld) shall be borne by TG. With respect to Global PMCs/PMRs arising following the Effective Date, TG will use Commercially Reasonable Efforts to develop and deliver to Company a budget for each such future Global PMCs/PMRs, provided that TG shall, prior to delivering such budget to Company, offer Company a reasonable opportunity to provide comments on the design, conduct and related budget of any future Global PMCs/PMRs and TG shall consider such comments in good faith; TG shall invoice Company, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by TG in connection with the

performance of such Global PMCs/PMRs in accordance with the applicable budget; provided that any costs exceeding such budget and not pre-agreed in writing by the Company (such consent not to be unreasonably withheld) shall be borne by TG. Notwithstanding the foregoing, for the avoidance of doubt, Company acknowledges and agrees that (i) the budgets set forth in Schedule 3.2.1(b) and/or otherwise provided in accordance with Section 3.2.1(b) are and will, at least initially, be estimates based on TG's proposals concerning the structure and conduct of each such study, (ii) such proposals are and shall be subject to review by the applicable Regulatory Authority(ies), (iii) TG shall have the right to adjust the budgets, from time to time, upon receipt of feedback and/or advice from the applicable Regulatory Authority(ies) by delivering to Company written notice of such adjustments and the rationale therefor, and, consequently, (iv) the resulting budget, as so adjusted, shall replace any prior draft budget and shall be the budget for such Global PMC/PMR.

(c)Product Improvement Development Activities. In the event that TG Develops a Product Improvement, Company shall have the option to obtain the exclusive commercialization right, on a Product Improvement-by-Product Improvement basis, to use such Product Improvement in connection with its Commercialization of the Product in the Field in the Territory. TG shall provide Company with written notice (each, a "*Product Improvement Notice*") of such Product Improvement and a brief description of the associated Development activities (the "*Product Improvement Development Activities*") as well as a break-down, in reasonable detail, of the costs actually incurred and likely to be incurred in the future by or on behalf of TG following the Effective Date in connection with the performance of the applicable Product Improvement Development Activities. In the event that Company notifies TG that it is exercising the option described in this Section 3.2.1(c) with respect to a particular Product Improvement within [***] ([***]) [***] of the delivery of the applicable Product Improvement Notice, then (i) the license granted in Section 2.1.1 shall include such Product Improvement, and

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(ii) TG shall invoice Company on a Calendar Quarterly basis, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by or on behalf of TG

following the Effective Date in connection with the performance of the applicable Product Improvement Development Activities. In the event that Company notifies TG that it is exercising the option described in this Section 3.2.1(c) later than [***] ([***]) [***] following the delivery of the Product Improvement Notice, then (i) the license granted in Section 2.1.1 shall include such Product Improvement, and (ii) TG shall invoice Company on a Calendar Quarterly basis, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by or on behalf of TG following the Effective Date in connection with the performance of the applicable Product Improvement Development Activities. Notwithstanding the foregoing, the Parties acknowledge and agree as follows:

(i)As regards any Product Improvement relating to establishing any alternative source for manufacturing and supplying the Product (drug substance and/or drug product), the exercise period for the exercise of the option pursuant to the foregoing shall not apply and the Company shall be entitled to exercise such right at any time during the Term and shall in such case be required to reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by or on behalf of TG following the Effective Date in connection with the performance of the applicable Product Improvement Development Activities.

(ii)As regards any MoA Product Improvement, in the event that Company fails to notify TG that it is exercising its option, or notifies TG that it is not exercising its option, with respect to such MoA Product Improvement within [***] ([***]) [***] following the delivery of the Product Improvement Notice, then Company shall have no rights with respect to such MoA Product Improvement, and, for clarity, TG shall have the right, whether itself or through its Affiliates or any Third Party, to Commercialize such MoA Product Improvement in the Territory; provided, however, that neither TG, its Affiliates nor a Third Party shall be entitled to Commercialize such MoA Product Improvement in the Territory under the Licensed Trademark.

(iii)For the avoidance of doubt, unless and until Company exercises its option with respect to a Product Improvement in accordance with this Section 3.2.1(c), Company shall not have any right to use such Product Improvement in the Territory, including, without limitation, that Company shall not benefit from any cost-savings that result from any CMC process improvement that constitutes a Product Improvement for which Company has not exercised its option.

(d)New CNS Indication Development Activities. In the event that TG Develops the Product for an Indication outside the Field that is indicated to treat a disease or condition of the central nervous system (each, a "*New CNS Indication*"), Company shall have the option to obtain an exclusive commercialization right, on a New CNS Indication-by-New CNS Indication basis, to use any Patents Rights and/or Technology arising as a result of or in connection with such New CNS Indication Development Activities (the "*New CNS Indication IP*"), to the extent necessary to Commercialize the Product for such New CNS Indication in the Territory. TG shall provide Company with written notice (a "*New CNS Indication Notice*") of such New CNS Indication for the Product and a brief description of the associated Development activities (the "*New CNS Indication Development Activities*") as well as a break-down, in reasonable detail, of the costs actually incurred and likely to be incurred in the future by or on behalf of TG following

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the Effective Date in connection with the performance of the applicable New CNS Indication Development Activities. In the event that Company notifies TG that it is exercising the option described in this Section 3.2.1(d) with respect to a particular New CNS Indication within [***] ([***]) [***] of the delivery of the applicable New CNS Indication Notice, then (i) the Parties shall enter into an addendum to this Agreement, pursuant to which the license granted in Section 2.1.1 shall be amended to include the applicable New CNS Indication IP and the Field shall be amended to reflect such New CNS Indication, (ii) TG shall invoice Company on a Calendar Quarterly basis, and Company shall reimburse TG, for [***] ([***]) of all reasonable costs actually incurred by or on behalf of TG following the Effective Date in connection with the performance of the applicable New CNS Indication Development Activities, and (iii) Company shall pay TG the milestone payments set forth in Section 8.2.1. In the event that Company fails to notify TG that it is exercising the option described in this Section 3.2.1(d) with respect to a particular New CNS Indication during such [***] ([***]) [***] period or otherwise notifies TG earlier that it will not exercise such option, then Company shall have no rights with respect to the Product for the New CNS Indication, and, for clarity, TG shall have the right, whether itself or through its Affiliates or any Third Party, to Commercialize the Product for such

New CNS Indication in the Territory; provided, however, that neither TG, its Affiliates nor a Third Party shall be entitled to Commercialize such New CNS Indication of the Product in the Territory under the Licensed Trademark.

3.2.2 **Company Development Activities. Company shall perform the Company Development Activities at its cost.**

3.3 **Development Diligence.**

3.3.1 **Company, and/or its Affiliates, Sublicensees, and Distributors shall use Commercially Reasonable Efforts during the Term to (a) conduct the Territory-Specific Requirements and, if approved in accordance with Section 3.1.3, the Optional Territory-Based Development Activities, and (b) commit, maintain, and use such resources (including employees, consultants, contractors, facilities, equipment, and materials) as necessary to conduct the Territory-Specific Requirements as needed to obtain and maintain Marketing Authorization(s) for the Product in the Field in the Territory in a timely manner. Without limiting the foregoing, Company's efforts described in this Section 3.3 shall comply with the diligence obligations set forth in the Hadam License.**

3.3.2 **TG shall use commercially reasonable efforts during the Term to (a) conduct the Global PMCs/PMRs and Territory-Specific CMC PMCs, and (b) commit, maintain, and use such resources (including employees, consultants, contractors, facilities, equipment, and materials) as necessary to conduct such Global PMCs/PMRs and Territory-Specific CMC PMCs.**

3.4 **Development Plan (Territory Growth). Attached hereto as Exhibit A is an initial Development Plan prepared by Company for the Product in the Field in the Territory, including the sequence of Company's anticipated activities to seek and obtain Marketing Authorization for the Product in the Field in the United Kingdom and additional countries and regions in the Territory, which are identified by Company as Company's commercial priorities. During the Term, Company shall prepare and provide to the JSC an updated Development Plan for the Product**

no later than [***] ([***]) [***] prior to the end of each Calendar Year. Company shall seek health authority scientific advice to determine the pivotal studies deemed necessary for Product registration in the Field in the Territory at the earliest possible time. The advice received should be reflected in updated Development Plans. In the event of any conflict between the terms of the Development Plan and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall prevail.

3.5 **Compliance. Each Party shall perform (and shall cause their respective Affiliates, licensees, and distributors to perform) (a) with respect to Company, the Company Development Activities, and (b) with respect to TG, Global PMCs/PMRs and Territory-Specific CMC PMCs, in each case, in good scientific manner and in compliance with all Applicable Laws. For purposes of clarity, with respect to such Development activities, each Party shall comply in all material respects with GLPs, GMPs, GVPs, and Good Clinical Practices (or, if and as appropriate under the circumstances, International Conference on Harmonization ("*ICH*") guidance or other comparable regulation and guidance of any Regulatory Authority in the Territory, as applicable).**

3.6 **Records; Reports.**

3.6.1 **Company's Obligations. Company and/or its Affiliates, Sublicensees, and Distributors shall (a) maintain records of its activities relating to the Company Development Activities in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work performed and results achieved in the performance of the Company Development Activities, and (b) keep the JSC regularly informed of the progress of the Company Development Activities, including without limitation, providing TG with an annual development report for the Product (each, a "*Development Report*") (to be delivered with each annual update to the Development Plan) that summarizes: (i) significant Development activities conducted by Company (or its Affiliates, Sublicensees, and/or Distributors) during the preceding Calendar Year and results obtained with respect to the Compound and Product (including the status of all Clinical Trials), (ii) Significant Development Events applicable to the Compound and/or Product, (iii) a summary of all Arising IP conceived or reduced to practice by Company (or its Affiliates, Sublicensees, and/or Distributors) over such period, (iv) a non-binding estimate of the expected timing of any milestone events with respect to the Product, and (v) such other information that Company has in its possession as may be reasonably requested from time to time by TG and/or the JSC. The Development Plan and**

each Development Report shall be deemed Company Confidential Information.

3.6.2 **TG's Obligations**. TG and/or its Affiliates, licensees, and distributors shall (a) maintain records of its activities relating to the Global PMCs/PMRs and Territory-Specific CMC PMCs in sufficient detail and in good scientific manner appropriate for regulatory purposes, which shall fully and properly reflect all work performed and results achieved in the performance of such activities, and (b) keep the JSC regularly informed of the progress of the Global PMCs/PMRs and Territory-Specific CMC PMCs. All such information disclosed to the JSC shall be deemed TG Confidential Information.

3.7 **Disclosure; Right of Access**. Upon request from TG, Company shall promptly provide TG with (a) a list of all sites at which Clinical Trials with respect to the Product in the Field are being conducted by or on behalf of Company as part of the Company Development

Activities; and (b) copies of all clinical trial protocols and associated regulatory documents with respect to such clinical trials. Additionally, Company shall promptly provide TG with access to all data (including non-clinical and Clinical Data), results, information, Patent Rights, and any other Technology arising as a result of, or generated by, the performance of the Company Development Activities (collectively, the "***Company Data***"). Company hereby grants TG a perpetual, irrevocable, exclusive, sublicensable, transferable, royalty-free, fully paid-up license to use the Company Data in connection with the Commercialization of the Product in the Excluded Territory and/or outside of the Field (whether in or outside the Territory) and/or the Development and/or Manufacture of the Product for any purpose.

3.8 **Clinical Trials in the Territory**. For clarity, nothing herein (including Section 7.4) shall restrict TG's right to (a) conduct, directly or indirectly, Clinical Trials and any other supporting activity, for any purpose, with respect to the Product in the Territory, provided that such Clinical Trials are not being conducted for the purpose of satisfying Territory-Specific Requirements, and/or (b) provide education concerning, discuss, or otherwise communicate with medical professionals and/or key opinion leaders in the Territory regarding any Clinical

Trials relating to the Product (whether conducted in the Territory or the Excluded Territory). TG shall keep Company reasonably informed regarding all material Development activities of the Product in the Field conducted in the Territory and all such education, discussions, and communications with medical professionals and/or key opinion leaders in the Territory. If Company reasonably believes that such Development activities may have a material negative effect on the Commercialization of the Product in the Field in the Territory, then Company shall deliver written notice to TG outlining such concerns in sufficient detail and TG shall review and consider such concerns in good faith, without any obligation on the part of TG to take any action or to refrain from taking any action in response to such concerns.

4. REGULATORY ACTIVITIES

For the sake of clarity, in this Article 4, Company means Company, and where applicable, its Affiliates, Sublicensees, and Distributors.

4.1 **Responsibility for Regulatory Filings. Company shall have the sole right, and shall be solely responsible for, the preparation and filing of all Regulatory Filings and Drug Approval Applications required to Commercialize the Product in the Field in the Territory in its own name, and Company shall have the sole right and responsibility for maintaining all Regulatory Filings and/or Marketing Authorizations for the Product in the Field in the Territory; provided, upon Company's reasonable request to TG, in the event that TG (by virtue of its knowledge of and experience with the Product) has background information and/or other expertise that could be useful in supporting Company's obligations set forth in this Section 4.1, then TG shall provide reasonable support and cooperation in connection with Company's obligations set forth in this Section 4.1; provided, further, however, that if any such reasonable support and cooperation is reasonably likely to require material and significant expenditure of resources, then the Parties shall discuss and agree in good faith the manner in which TG may reasonably support Company and reasonable compensation to TG by Company in light of any such material expenditures, prior to proceeding; provided, further, however, that Company shall be entitled to factor in any such compensation to TG when determining whether it is for Company commercially reasonable to Commercialize the Product in the Field in the relevant part of the Territory. For the avoidance of**

doubt, Company shall not make any filings with or commitments to any Regulatory Authority(ies) in the Territory that describe and/or bind the performance or function of the SBL Supply Chain (as defined in the Supply Agreement), including, without limitation, any aspect of the Manufacturing Process (as defined in the Supply Agreement), and/or that otherwise relate to the Manufacture of the Product, without TG's prior written consent. To maximize market protection of the Product in the Field, Company shall, if appropriate, file for any orphan drug designations within requisite timeframes; provided, however, that the Parties acknowledge and agree that any such orphan drug designation and any other regulatory exclusivity shall not prevent TG from exercising its rights relating to the Compound and/or Product in the Territory (whether outside the Field, with respect to an MoA Product Improvement or a New CNS Indication for which Company does not exercise its option, and/or with respect to a ROFN Product for which the Parties do not enter into a definitive agreement), and Company shall cooperate, take any steps or actions, and execute and deliver any and all documents and/or instruments necessary or helpful to support TG's full and complete enjoyment of its rights (including, without limitation, before any applicable Regulatory Authority). Company shall obtain and maintain Marketing Authorizations with respect to the Product in the Field in the European Union and any other Key Market, and shall use Commercially Reasonable Efforts to obtain and maintain Marketing Authorizations with respect to the Product in the Field in the remainder of the Territory, including in accordance with the timelines reasonably requested by TG. For the avoidance of doubt, the Parties acknowledge and agree that Company's failure to meet the obligations set forth in this Section 4.1 shall be considered a material breach of this Agreement, and TG will have the right to terminate this Agreement in accordance with Section 11.2.2, in addition to any other rights or remedies available at law or in equity. Company hereby grants TG and its Affiliates and licensees a right of reference with respect to all Regulatory Filings, Drug Approval Applications, Marketing Authorizations, and other Regulatory Approvals relating to the Product for the purpose of Commercializing the Product (a) inside and/or outside the Field in the Excluded Territory, and (b) outside the Field within the Territory, and otherwise for the purpose of Developing and/or Manufacturing the Product.

4.2 **Marketing Authorization.**

4.2.1 **Marketing Authorization Holder. Company shall be the holder of all Regulatory Approvals of the Product in the Field in the Territory, including the holder of the Marketing Authorization for the Product in the Field in the Territory.**

4.2.2 **Marketing Authorization Transfer. The Marketing Authorization marketing the Product in the Field in the European Economic Area has been issued by receipt of the decision of the European Commission on 1 June 2023 (ref. EU/1/23/1730 - EMEA/H/C/005914/0000). Promptly after the Effective Date, TG shall, without undue delay, procure that the then current holder of the Marketing Authorization transfers such Marketing Authorization to Company. With respect to such Marketing Authorization transfer, TG shall use commercially reasonable efforts to (a) execute and/or deliver all necessary regulatory documents required for such Marketing Authorization transfer, (b) provide Company with reasonable assistance in connection with the consummation of such Marketing Authorization transfer, at Company's cost and expense, and (c) provide Company with copies of the materials identified on Schedule 4.2.2(c).**

4.3 **Disclosure of Certain Events. The Parties hereby, agree to report to each other all Adverse Events and/or Serious Adverse Events with respect to the Product in the Field in the**

Territory without undue delay after having obtained knowledge of such events, within timeframes consistent to enable the reporting party to comply with reporting obligations under Applicable Laws, and, subject to the foregoing, no later than (i) [***] ([***]) [***] for reporting the source documentation of any Serious Adverse Events, (ii) [***] ([***]) [***] to provide the formal report of a Serious Adverse Event and (iii) quarterly for Adverse Events, which reports shall, in each case of (ii) and (iii), include the circumstances and nature of such Serious Adverse Event or Adverse Event as required for reporting under Applicable Laws. In addition, to the extent requested by either Party, the other Party shall promptly provide to the requesting Party any other information or materials that the requesting Party may require to provide to any Regulatory Authority with respect to any such Adverse Event or Serious Adverse Event. All disclosures made

under this Section 4.2 shall be deemed the Confidential Information of both Parties; provided, however, that nothing herein shall restrict, in any way, either Party's ability to report the occurrence, circumstances and nature of such Adverse Event and/or Serious Adverse Event to any Regulatory Authority solely insofar as such reporting is reasonably required to comply with Applicable Laws. TG shall be solely responsible for holding and maintaining a global safety database for the Product. No later than [***] ([***]) [***] following the Effective Date, the Parties shall enter into a global pharmacovigilance and safety agreement, on customary terms.

4.4 **Communication with Regulatory Authorities in the Territory. Company shall have the sole right, and shall be solely responsible for, all communications with any Regulatory Authority regarding the Product in the Field in the Territory, except with respect to Global Development Activities that take place in the Territory (for which TG shall have the sole right to communicate with the applicable Regulatory Authorities in accordance with Section 4.6); provided, however, that Company shall promptly (a) notify TG of any information received regarding any threatened or pending action by any Regulatory Authority that might affect the Product or continued Commercialization of the Product in the Field in the Territory, and (b) provide TG with copies of all material correspondence with any Regulatory Authority, to the extent related to the Product in the Field in the Territory, including, without limitation, correspondence relating to (i) Drug Approval Applications, Marketing Authorizations, or other Regulatory Approvals, (ii) regulatory actions, and (iii) recalls (whether voluntary or mandatory). TG shall be entitled to review and provide comments on any proposed material communication with any Regulatory Authority relating to the Product in the Field in the Territory, and Company shall consider all such comments in good faith; provided, however, that, notwithstanding the foregoing, Company's obligation to consult with TG shall be subject to Company's good faith determination that the time required to so consult would not materially impair the availability of rights or remedies, or increase exposure, in connection with such communication. Company will use commercially reasonable efforts to submit communications to Regulatory Authorities relating to the Product in the Field in the Territory in accordance with timelines reasonably requested by TG. Company shall keep the JSC reasonably informed regarding any non-routine communications with any Regulatory Authority in connection with the Product in the Field in the Territory, Drug Approval Application, Marketing Authorization, or other Regulatory Approval, including any additional Development work required by any Regulatory Authority with respect to the Product in the Field in the Territory.**

4.5 **Meeting with Regulatory Authorities in the Territory. Company shall use reasonable efforts to provide TG with at least [***] ([***]) [***] advance notice of any meeting with any Regulatory Authority in the Territory regarding the Drug Approval Application or Marketing**

Authorization for the Product in the Field, or any inspection to be conducted by any Regulatory Authority at any site which Clinical Trials with respect to the Product in the Field are being conducted by or on behalf of Company, and TG may elect to send one (1) person to participate as an observer (at TG's sole cost and expense) in such meeting or inspection.

4.6 **TG's Communications with Regulatory Authorities. Notwithstanding any provision to the contrary, TG shall have the sole right to communicate and make filings with any Regulatory Authority in the Territory with respect to any Global Development Activities relating to CMC and/or any other Development activities conducted by or on behalf of TG with respect to the Product in the Territory (whether within or outside the Field). TG shall keep Company reasonably informed of its interactions with Regulatory Authorities to the extent relating to the Product in the Field in the Territory. Upon TG's request, Company shall cooperate in connection with such activities and communications, including, without limitation, Company shall make any filings and/or send any communications to the applicable Regulatory Authority in the Territory with respect to such Global Development Activities relating to CMC and/or such other Development activities in accordance with TG's instructions (for clarity, whether or not Company exercises its option in accordance with Section 3.2.1(c), as applicable) and shall otherwise take any steps or actions and execute and deliver any and all documents and instruments necessary or useful to support TG's exercise of its right to conduct the activities contemplated hereby, including, without limitation, to the extent required under Applicable Law, a power of attorney authorizing TG to communicate and make filings with such Regulatory Authority in the Territory with respect to Global Development Activities relating to CMC and/or such other Development Activities.**

5. COMMERCIALIZATION

For the sake of clarity, in this Article 5, Company means Company, and where applicable, its Affiliates, Sublicensees, and Distributors.

5.1 Commercialization Plan. Company's Commercialization Plan for the Product in the Field in the Territory is attached hereto as Exhibit B. During the Term, Company shall update the Commercialization Plan for the Product in the Field in the Territory annually and deliver such updated Commercialization Plan(s) to TG no later than [***] ([***]) [***] prior to the end of each Calendar Year. Without limiting the generality of Section 1.26, each Commercialization Plan shall include a market penetration and market coverage, launch (as applicable), and sales plan, including minimum net revenues and the size of the proposed sales force, as well as integration with medical information, key opinion leader (KOL) engagement, and size and positioning of medical science liaisons (MSLs) for the [***] ([***]) [***] period immediately following the submission of such Commercialization Plan (the "[***]-[***] *Commercialization Plan*"). The [***]-[***] Commercialization Plan shall be reasonably powered, including with financial and personnel resources (including both sales and medical affairs and support resources) to achieve the market potential as set forth in Schedule 5.1. Year over year, Company shall not materially reduce any commitments (including, without limitation, resources, finances, and/or minimum net revenues) set forth in the [***]-[***] Commercialization Plan, without TG's prior written consent in its sole discretion.

5.2 Responsibility for Commercialization. Company shall have the primary right and responsibility for, and shall have primary control and authority over, at its sole cost and expense,

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(a) all aspects of the Commercialization of the Product in the Field in the Territory including the sole responsibility for booking sales of the Product in the Field in the Territory and for all returns, charge-backs, and rebates with respect to the Product in the Field in the Territory; and (b) the conduct of all pre-marketing, marketing, Branding (subject to Section 2.1.3), promotion, sales, distribution, import and export activities (including securing pricing, reimbursement, and sales and marketing), and market access activities (including, without limitation, pricing and public funding) applicable

to the Commercialization of the Product in the Field in the Territory.

5.3 **Commercialization Diligence.**

5.3.1 **Company shall use Commercially Reasonable Efforts to Commercialize the Product in the Field in the Territory. The use of such Commercially Reasonable Efforts shall include that Company shall execute and comply with the [***]-[***] Commercialization Plan; provided, however, that such execution and compliance shall not, alone, be sufficient to demonstrate satisfaction of the diligence obligation set forth in this Section 5.3.1.**

5.3.2 **Without limiting the generality of Section 5.3.1:**

(a)Company shall (i) to the extent legally permissible under Applicable Laws, commencing no later than [***] ([***]) [***] prior to the estimated date of First Commercial Sale of the Product in the Field in the Territory, conduct pre-marketing activities in the Territory with respect to the Product, (ii) following receipt of Marketing Authorization with respect to the Product in the Field in the Territory, initiate and conduct such promotional activities determined by Company as may be required to develop a commercial market for, launch, and Commercialize the Product (including through direct conduct with key opinion leaders) in the Territory, and (iii) no later than [***] ([***]) [***] following the receipt of Marketing Authorization (and, if applicable, Pricing Approvals and Reimbursement Approvals) with respect to the Product in the Field in a given country in the Territory, complete the First Commercial Sale of the Product in such country. Notwithstanding any provision to the contrary, in the event that Company desires to engage key opinion leaders or other medical professionals based in the Excluded Territory for the purpose of developing a commercial market for, launching, and/or otherwise Commercializing the Product in the Territory, then Company shall provide TG with prior written notice and the Parties shall discuss and cooperate in good faith.

(b)Company shall establish and maintain a well-trained sales force for the Product in the Field in the Territory (including, for the avoidance of doubt, in accordance with the commitments set forth in the [***]-[***] Commercialization Plan and Section 5.3.2(c)), together with a well-trained support staff, adequate to service all the customers of Company and to ensure Coverage (as defined in Section 2.3 of the initial Commercialization Plan attached hereto as Exhibit B) at all Key Multiple Sclerosis Centers in the Territory; keep the sales force knowledgeable and fully informed as to the

Product in the Field in the Territory; provide appropriate incentives consistent with normal business practices to sales representatives involved in the Commercialization of the Product in the Field in the Territory; maintain an effective distribution system for the Product in the Field in the Territory; transport and store the Product to preserve its quality in accordance with pre-determined QA requirements; obtain and maintain all licenses, approvals, and permits in the Territory necessary for Company to perform its obligations under this Agreement; establish and maintain suitable systems and records to enable a recall of

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Product in a timely, efficient, and accurate manner and otherwise in accordance with Applicable Laws; comply with all Applicable Laws, including, without limitation, those relating to sales, marketing, and reimbursement; without limiting the generality of the foregoing, ensure that no Product shipped by Company is adulterated or misbranded; maintain adequate control over the physical security of the Product; and cause all Affiliates, Sublicensees and subcontractors of Company to comply with Company's obligations set forth herein.

(c)Company shall recruit and retain, following the Effective Date, new employees who will be dedicated to the Product in the Field in the Territory and who will perform the following activities: (i) medical representatives or medical science liaisons who perform in-person presentations of the Product in the Field to health care professionals in the Territory, and (ii) sales representatives and/or key account managers who perform sales calls in the Territory (each of (i) and (ii), a "*New Sales Representative*"), all in accordance with the [***]-[***] Commercialization Plan. Company shall (A) ensure that each New Sales Representative has no less than [***] ([***]) [***] direct experience in the Multiple Sclerosis therapeutic category, and (B) ensure that each New Sales Representative has, in Company's reasonable view, established relationships with key opinion leaders and other stakeholders in their respective geographic regions. All New Sales Representatives shall undergo training prior to entering the field and engaging with potential customers. Company's training materials shall be consistent, in all respects, with any training materials provided by TG.

(d)Company's efforts described in this Section 5.3 shall comply with the diligence obligations set forth in the Hadam License.

5.3.3 **For the avoidance of doubt, the Parties acknowledge and agree that the failure to meet any of the obligations set forth in this Section 5.3 shall be considered a material breach of this Agreement, and TG will have the right to terminate this Agreement in accordance with Section 11.2.2, in addition to all other rights and remedies available to TG at law or in equity, provided that Company's failure to meet any of the obligations set forth in this Section 5.3 shall not be considered a material breach of this Agreement if such failure is due to Company not being supplied with the amount of Product ordered under the Supply Agreement (for whatever reason, but excluding Company's fault, and provided that Company has satisfied its safety stock obligations set forth in the Supply Agreement and has exhausted its safety stock of the Product). If TG exercises its termination right under this Section 5.3.3, notwithstanding anything to the contrary in Section 11.2.2, it shall provide ninety ([***]) [***] prior written notice of termination. If during the above mentioned [***] ([***]) [***] period Company cures such breach, then the termination shall be null and void.**

5.4 **Medical Information and Materials. Without limiting the generality of the foregoing:**

5.4.1 **Medical Information. Company shall handle all medical questions or inquiries from members of the medical profession in the Territory regarding the Licensed Product in the Field. To the extent that any inquiry relates to a medical matter for which TG has already provided a medical information answer or is the subject of a prepared medical response, Company agrees to use such materials to ensure consistent global medical information dissemination. If a new inquiry arises, the Parties agree to discuss the issue and formulate a jointly agreeable response.**

For the avoidance of doubt, Company shall not respond to any medical question or inquiry in the Excluded Territory.

5.4.2 **Medical Materials. Company shall obtain the written approval of TG with respect to all materials prepared by Company with respect to the Product in the Field for use in the Territory, prior to the**

first use thereof, such approval (or rejection or other comments) to be provided by TG within [***] ([***]) [***] of receiving such medical materials; provided, however, that Company acknowledges and agrees that it shall be responsible for ensuring, and shall ensure, compliance of such medical materials with Applicable Laws and Marketing Authorizations and consistency with medical materials used by TG in the Excluded Territory and made available by TG to Company.

5.5 **Failure to Achieve Sales Targets**

5.5.1 **Initial Period. For the first [***] ([***]) Commercial [***] following the date of First Commercial Sale in the Territory (the "*Initial Period*"), Company shall achieve the Sales Target for the Product in the Field in the Territory. If Company fails to achieve [***] ([***]) of the Sales Target for the Product in the Field in the Territory by completion of the Initial Period, Company shall, within [***] ([***]) [***] of the end of the second Commercial Year, pay to TG a sum equal to the difference between the royalties paid on actual sales of the Product in the Field in the Territory and the royalties payable for [***] of the Sales Target for the Product in the Field in the Territory for the Initial Period; provided, however, that such payment obligation shall not apply if the failure to achieve the Sales Target is due to a Product supply failure not attributable to Company (provided that Company has satisfied its safety stock obligations set forth in the Supply Agreement and has exhausted its safety stock of the Product). For clarity, failure to achieve the Sales Target only applies if the First Commercial Sale already occurred in the Territory. For purposes of this Agreement, "*Commercial Years*" means, with respect to the Product, the period commencing on the date of First Commercial Sale of the Product in the Field in the Territory and ending on the anniversary thereof and thereafter each successive period of [***] ([***]) [***].**

5.5.2 **Subsequent Periods. During each Commercial Year following the Initial Period, Company shall achieve the Sales Target for the Product in the Field in the Territory. If Company fails to achieve [***] ([***]) of the Sales Target for the Product in the Field in the Territory during any Commercial Year following the Initial Period, Company shall, within [***] ([***]) [***] of the end of such Commercial Year, pay to TG a sum equal to the difference between the royalties paid on actual sales of the Product in the Field in the Territory and the royalties payable for [***] of the Sales Target for the Product in the Field in the Territory for such Commercial Year; provided, however, that such payment obligation shall not apply if the failure to achieve the Sales Target is due to a Product supply failure not attributable to Company (provided that Company has satisfied its safety stock obligations set**

forth in the Supply Agreement and has exhausted its safety stock of the Product). For clarity, failure to achieve the Sales Target only applies if the First Commercial Sale already occurred in the Territory.

5.5.3 Right to Terminate. Without limiting the generality of Sections 5.5.1 and 5.5.2, if LFB has sent or has threatened TG in writing to send to TG a termination notice pursuant to section 5.5.2 para. 2 of the LFB License (i.e., based on the grounds that TG failed to achieve [***] ([***]) of the sales targets applicable under the LFB License for [***] ([***]) consecutive

commercial [***]), then TG shall have the right to terminate this Agreement pursuant to and in accordance with Section 11.2.4 with respect to country(-ies) within the Territory where [***] of the Sales Targets for the Product in the Field in such country were not achieved and in relation to which LFB has terminated or threatened in writing to terminate the LFB License. In the event that, following termination of this Agreement pursuant to Section 11.2.4 with respect to a given country(-ies) in the Territory, TG retains the right to Commercialize the Product in the Field in such terminated country(ies) and TG desires to grant to a Third Party rights in and to sell, offer to sell, import, have imported, market and otherwise Commercialize the Product in the Field in such terminated country(ies), then TG shall, to the fullest extent permissible under Applicable Law (including, but not limited to, in compliance with all vertical block exemptions or their equivalent legislations or caselaw), contractually limit such grant of rights to the territory of the terminated country(-ies), and TG shall use commercially reasonable efforts, consistent with Applicable Law, to enforce such right *vis-à-vis* the respective Third Party in the event that TG learns of a breach of such limitations.

5.5.4 Acknowledgement. For clarity, the remedies set forth in this Section 5.5 shall be in addition to any other rights and remedies available to TG at law or in equity, including under Section 11.2.2.

5.6 No Unauthorized Sales. To the fullest extent permissible under Applicable Law, Company shall not, and shall not permit its Affiliates, Sublicensees, or Distributors to, directly or indirectly, (a) distribute, market, promote,

offer for sale, sell, or otherwise Commercialize the Product to any customer inside or outside the Territory for subsequent sale in the Excluded Territory; (b) deliver or tender (or cause to be delivered or tendered) the Product in the Excluded Territory for use in the Excluded Territory; or (c) sell the Product to, or solicit Product sales from a customer in the Territory if Company (or its Affiliate, Sublicensee, or Distributor, as applicable) knows or has a reasonable basis to conclude that such Third Party intends to resell the Product in the Excluded Territory. To the extent legally permissible under Applicable Laws, the packaging of the Product shall be clearly marked, in applicable language(s), "Not for export to or distribution in any of the following: the United States, Canada, Mexico, South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar." Without limiting the generality of the foregoing, Company shall (x) establish and implement programs, internally and with Affiliates, Sublicensees, and Distributors, to confirm compliance with this Section 5.6; (y) deliver reports to TG, on a Calendar Quarter basis and otherwise upon TG's request, that confirm compliance with this Section 5.6 during the immediately preceding Calendar Quarter or other time period reasonably requested by TG; and (z) in any event, respond promptly to TG's requests regarding the subject matter of this Section 5.6 and take all measures permitted under Applicable Law to address any violations or suspected violations of this Section 5.6 that TG reports to Company or of which Company otherwise becomes aware. In addition, and in addition to any other rights and remedies available at law or in equity, in the event that Product Commercialized by or on behalf of Company (or its Affiliates, Sublicensees, or Distributors) is subsequently sold in the Excluded Territory, then Company shall reimburse TG for all lost profits arising as a result thereof, to the maximum extent permissible under Applicable Law.

5.7 **Records; Reports. Company shall (a) maintain records of its Commercialization activities under this Article 5 in sufficient detail that shall fully and properly reflect all work done and results achieved in the Commercialization of the Product in the Field in the Territory, and (b)**

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following the commencement of Commercialization of the Product in the Field in the Territory and substantially

simultaneous with the delivery of the Commercialization Plan in accordance with Section 5.1, provide TG with annual written reports (each, a "*Commercialization Report*"), that shall (i) summarize Company's efforts to Commercialize the Product in the Field in the Territory, (ii) identify the Regulatory Filings and Drug Approval Applications with respect to the Product that Company or any of its Affiliates or Sublicensees have filed, sought, or obtained in the prior [***] ([***]) [***] period or reasonably expect to make, seek, or attempt to obtain in the following [***] ([***]) [***] period, and (iii) summarize all Clinical Data and other Company Data generated by Company with respect to the Product. Commencing no later than [***] ([***]) [***] from the date of receipt of the first Marketing Authorization for the Product in the Territory and on each anniversary thereof until the termination of this Agreement, each such Commercialization Report shall also include (i) an outline of the key sales and marketing activities that Company reasonably expects to conduct with respect to the Product in the Territory, (ii) a non-binding estimate of projected sales of the Product in the Territory for the subsequent [***] [***]) Calendar [***] period, and (iii) such additional information that it has in its possession as may be reasonably requested by TG regarding the Commercialization of the Product, which request shall not be made more than once each Calendar [***]. The Commercialization Plan and Commercialization Report can be provided as one document.

5.8 **Product Recalls. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with the Product in the Field in the Territory, or in the event Company reasonably believes that an event, incident, or circumstance has occurred that may result in the need for a recall, market withdrawal, or other corrective action regarding the Product in the Field in the Territory (each, a "*Recall*"), such Recalls shall be handled in accordance with Section 8.2 of the Supply Agreement.**

6. SUPPLY

Simultaneously with entry into this Agreement, the Parties are entering into a master services agreement dated as of the date hereof, together with a product specific agreement – commercial drug substance dated as of the date hereof (the "*DS PSA*") and a product specific agreement – commercial drug product dated as of the date hereof (the "*DP PSA*," and together with the aforementioned master services agreement and DS PSA, the "*Supply Agreement*"), pursuant to which (a) TG shall supply Company with Product manufactured by TG's third-party supplier primarily in the form of US/EU harmonized Product, and (b) Company shall purchase such Product, on

an exclusive basis, from TG, for the sole purpose of Commercialization of Product in the Field in the Territory.

7. JSC

7.1 **Formation**. Promptly following the Effective Date, the Parties shall establish a joint steering committee (the "*JSC*") consisting of up to three (3) representatives designated by each Party, with appropriate knowledge and expertise. The JSC shall operate in accordance with the provisions of this Article 7, and shall have no authority to alter or amend the terms and conditions of this Agreement. A Party may change one (1) or more of its representatives serving on the JSC at any time upon written notice to the other Party. Each Party may invite additional personnel of such Party to any regular or special JSC meeting; provided, however, any such additional invitee shall (a) not be deemed a member of the JSC; and (b) with respect to any Confidential Information

of either Party such additional invitee learns, obtains, or otherwise has access to as a result of such invitation, be subject to confidentiality obligations and restrictions on use no less stringent than those set forth in Article 9, which such confidentiality obligations and restrictions on use shall be valid and enforceable by the Party whose Confidential Information is involved.

7.2 **JSC Responsibilities**. The JSC shall serve as a forum for the Parties to share information regarding the Development, Manufacture, and Commercialization of the Product in the Field in the Territory and to facilitate coordination between the Parties, but shall not have any decision-making authority with respect to the Parties' activities under this Agreement except as set forth in Section 7.3 and Section 7.4. At each meeting, Company shall provide updates and forecasting relating to all Development and Commercialization activities conducted by or on behalf of Company relating to the Product in the Field in the Territory, including any information requested by TG from time to time.

7.3 **Development and Commercialization Plans**. Company shall, prior to the JSC meeting held during the fourth Calendar Quarter of each year during the Term, deliver to the JSC drafts of the Development Plan, Development Report, Commercialization Plan, and/or Commercialization Report, as applicable, for the Product

in the Field in the Territory. Representatives designated by TG shall have a reasonable opportunity at such fourth Calendar Quarter JSC meeting (and any time thereafter) to comment upon and advise on such Development Plan(s), Development Report(s), Commercialization Plan(s), and Commercialization Report(s), and Company shall consider all such comments and advice in good faith. Each year during the Term, the JSC shall use commercially reasonable efforts to reach a consensus upon and unanimously approve the Development Plan(s) and the Commercialization Plan(s), with each Party having a single vote irrespective of the number of representatives of such Party in attendance. The Parties agree that TG shall not withhold approval of any Commercialization Plan, provided that such Commercialization Plan (including, for the avoidance of doubt, the [***]-[***]Commercialization Plan) provides that: (a) with respect to any given Calendar Year from [***] until and including [***], Company's overall expenditures shall be, at a minimum, *the higher of* (i) [***]. For the avoidance of doubt, each forecast made by Company under this Agreement shall be made in good faith and based on reasonable assumptions derived from relevant data at the time prepared by Company in the exercise of its Commercially Reasonable Efforts. If the JSC cannot reach consensus or otherwise agree upon any Development Plan or Commercialization Plan, then either Party shall have the right to refer such disputed issues to the Chief Executive Officers (CEOs) of the Parties for resolution. If, notwithstanding good faith, diligent efforts, the CEOs fail to reach a resolution with respect to any such disputed issues relating to the Development Plan(s) and/or Commercialization Plan(s) within [***] ([***]) [***] of such initial referral to the CEOs, then either CEO shall have the right to refer such disputed issues to binding arbitration, which shall be conducted as set forth in Schedule 7.3(B). Notwithstanding any provision to the contrary, the Parties acknowledge and agree that approval by TG representatives of such Development Plan(s), Development Report(s), Commercialization Plan(s), and/or Commercialization Report(s), and Company's satisfaction of such plans and/or reports, shall not themselves be determinative of whether Company has satisfied its diligence obligations set forth in this Agreement.

7.4 **TG EU Commercial Personnel. In each JSC meeting, TG shall inform Company of any proposed activities of the TG EU Commercial Personnel. The JSC shall discuss and agree on**

any such activities (including the key opinion leaders involved, the sequence of timing of interactions with the concerned key opinion leaders by the TG EU Commercial Personnel and personnel of Company, and any materials used by TG EU Commercial Personnel when performing these activities), provided that TG EU Commercial Personnel shall not perform any activity in the Territory without prior discussion and agreement by the JSC.

7.5 **Meetings**. The JSC shall meet at such times and frequency mutually agreed by the Parties at locations mutually agreed by the Parties, but no less frequently than Calendar Quarterly during the Term; provided that such meetings may be held by audio or video teleconference at the request of either Party. Each Party shall bear its own costs associated with the attendance of its appointees at such meetings. A secretary shall be appointed for each meeting of the JSC and shall prepare draft minutes of the meeting promptly following the meeting and shall circulate such draft minutes for comment and finalization by the Parties.

7.6 **Working Groups**. The JSC shall, from time to time, establish working groups to facilitate timely dialogue and coordination. The topics for such working groups may include, without limitation, CMC/quality, pharmacovigilance, Commercialization, and regulatory and Development. Each Party shall have the right to appoint to each such working group an equal number of representatives as mutually agreed by the Parties, each with appropriate knowledge and expertise. Without limiting the generality of the foregoing, promptly following the Effective Date, the JSC shall establish a Commercialization working group (the "*CWG*") as further described on Exhibit E attached hereto and a supply chain joint working committee as further described in the Supply Agreement.

8. PAYMENTS

8.1 **Upfront Payment**. Substantially simultaneous with entry into this Agreement, Company shall pay TG a one-time, non-refundable payment of $140,000,000 (the "*Upfront Payment*").

8.2 **Milestone Payments**.

8.2.1 **Milestones**. Company shall make the following non-refundable, non-creditable payments to TG (the "*Milestone Payments*") upon the occurrence of each of the following milestone events:

	Milestone Event	Milestone Payment
1.	Commercial launch of the Product in the Field and, in the event that Company exercises its right to license any New CNS Indication IP in accordance with Section 3.2.1(d), for each such New CNS Indication, in the first Key Market	$12,500,000
2.	Commercial launch of the Product in the Field in the last of all Key Markets and, in the event that Company exercises its right to license any New CNS Indication IP in accordance with Section 3.2.1(d), for each such New CNS Indication	$[***]
3.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
4.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
5.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]

6.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
7.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
8.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
9.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
10.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]
11.	Achievement of €[***] Net Sales, in aggregate, of the Product in the Field in the Territory in a Calendar Year	$[***]

For clarity, in the event that Company exercises its right to license any New CNS Indication IP in accordance with Section 3.2.1(d), then Net Sales for all Products in the Field (including the New CNS Indication in accordance with the addendum to this Agreement contemplated by Section 3.2.1(d)) shall be aggregated for purposes of calculating milestones 3-11 above and for purposes of calculating royalties in accordance with Section 8.3.

8.2.2 **Notice and Payment of Milestones.**

(a)Notice of Milestone Events. Company shall provide TG with prompt written notice upon the occurrence of each milestone event set forth in Section 8.2.1, and no later than (i) with respect to milestones 1 and 2, [***] ([***]) [***] following the occurrence of such milestone event, and (ii) with respect to milestones 3-11, [***] ([***]) [***] following the conclusion of such Calendar Year. Company shall pay TG the applicable Milestone Payment substantially simultaneous with delivery of the applicable notice in accordance with the foregoing sentence. In the event that, notwithstanding the fact that Company has

not given such a notice, TG believes any such milestone event has occurred, it shall so notify Company in writing and shall provide to Company data, documentation, or other information that supports its belief. Any dispute under this Section 8.2.2(a) that relates to whether or not a milestone event has occurred shall be resolved in accordance with Section 14.1.

(b)Acknowledgement. The Parties acknowledge and agree that, with respect to milestones 3-11, in the event that more than one (1) milestone is achieved during a given

Calendar Year, all such corresponding Milestone Payments shall be due simultaneously within [***] ([***]) [***] of the conclusion of such Calendar Year.

8.3 Payment of Royalties; Accounting and Records.

8.3.1 Payment of Royalties. Subject to the remainder of this Section 8.3, during the Term, Company shall make non-refundable, non-creditable royalty payments to TG, as follows:

(a)[***] of Net Sales, with respect to that portion of Net Sales of the Product in the Field in the Territory, in aggregate, in a given Calendar Year that is less than or equal to €[***];

(b)[***] of Net Sales, with respect to that portion of Net Sales of the Product in the Field in the Territory, in aggregate, in a given Calendar Year that is greater than €[***], but less than or equal to €[***];

(c)[***] of Net Sales, with respect to that portion of Net Sales of the Product in the Field in the Territory, in aggregate, in a given Calendar Year that is greater than €[***], but less than or equal to €[***]; and

(d)[***] of Net Sales, with respect to that portion of Net Sales of the Product in the Field in the Territory, in aggregate, in a given Calendar Year that is greater than €[***].

8.3.2 Payment Dates and Reports. Royalty payments shall be made by Company with respect to the Product in the Field in the Territory within thirty (30) days after the end of each Calendar Quarter in which sales of the Product occur, commencing with the Calendar Quarter

in which the First Commercial Sale of the Product occurs. Company shall also provide, at the same time each such payment is made, a report showing: (a) the Net Sales of the Product, by country in the Territory; (b) the total amount of deductions from gross sales to determine Net Sales; (c) a calculation of the amount of royalty due to TG; and (d) in the event that a Third Party is selling a Biosimilar Product in any country in the Territory and Company claims to be entitled to reduce its Royalty obligations in accordance with Section 8.3.5, then the sales of the Biosimilar Product in such Calendar Quarter as its relates to Company's [***] (as measured by [***] or other similar information available in such country), in a form adequate for TG to fulfill its obligations to LFB under Section 7.3.3 of the LFB License.

8.3.3 **Records; Audit Rights. Company and its Affiliates, Sublicensees, and Distributors shall keep and maintain for a minimum of [***] ([***]) [***]from the date of each payment of Milestone Payments and/or royalties hereunder complete and accurate records of gross sales and Net Sales and achievements of milestones by Company and its Affiliates, Sublicensees, and Distributors of the Product, in sufficient detail to allow Milestone Payments and/or royalties to be accurately determined. TG shall have the right for a period of [***] ([***]) [***] after receiving any such payment to appoint at its expense an independent certified public accountant reasonably acceptable to Company to audit the relevant records of Company and its Affiliates, Sublicensees, and Distributors to verify that the amount of each such payment was correctly determined; provided, that, (a) if requested by Company, TG shall cause the independent certified public**

accountant to enter into a confidentiality agreement reasonably acceptable to Company, and (b) such independent certified public accountant may only disclose to TG whether the amounts paid are correct and the details with respect to any discrepancies. Company and its Affiliates, Sublicensees, and Distributors shall each make its records available for audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon [***] ([***]) [***] written notice from TG. Such audit right shall not be exercised by TG more than once in any Calendar Year, unless good cause exists. All records made available for audit shall be deemed to be

Confidential Information of Company. The results of each audit, if any, shall be binding on both Parties absent manifest error. In the event there was an underpayment by Company hereunder, Company shall promptly (but in any event no later than [***] ([***]) [***] after Company's receipt of the report so concluding) make payment to TG of any shortfall. TG shall bear the full cost of such audit unless such audit discloses an underpayment by Company of [***] ([***]) or more of the aggregate amount payable by Company to TG hereunder in any Calendar Year, in which case Company shall reimburse TG for all costs incurred by TG in connection with such audit.

8.3.4 **Overdue Payments. All payments not made within the time period set forth in this Agreement shall bear interest at the rate of [***] ([***]) per month until paid in full or, if less, the maximum interest rate permitted by Applicable Laws. Any such overdue payment shall, when made, be accompanied by, and credited first to, all interest so accrued.**

8.3.5 **Royalty Reductions for Biosimilar Product. In the event that a Third Party commercializes a Biosimilar Product in any country in the Territory during any Calendar Quarter, then during the period in which sales of the Biosimilar Product by such Third Party in such country are equal to at least [***] ([***]) of Company's [***] in such country (as measured by [***]), the royalty payable to TG solely with respect to such country shall be reduced by [***] ([***]) of the royalty rate set forth in Section 8.3.1 that would otherwise be applicable with respect to Net Sales of such Product in such country; provided, however, that in the event that, in any subsequent Calendar Quarter, sales of such Biosimilar Product account for less than [***] ([***]) of Company's [***] in such country, the foregoing reduction shall no longer apply and Company shall pay the royalty payments in accordance with Section 8.3.1, without reduction, for all subsequent Calendar Quarters during the Term. Schedule 8.3.5 sets forth, for illustration purposes only, example calculations of the royalty reduction described in this Section 8.3.5.**

8.3.6 **Payments; Taxes; Currency Restrictions.**

(a)Payments in United States Dollars. Except as set forth in Section 8.3.5(b) below, all payments made by Company under this Article 8 shall be made by wire transfer in United States Dollars in accordance with wire transfer instructions provided to Company in writing from time to time by TG. If in any Calendar Quarter, Net Sales are made in any currency other than United States Dollars, such Net Sales shall be converted into United States Dollars as follows:

(A/B), where

A = foreign "Net Sales" (as defined above) in such Calendar Quarter expressed in such foreign currency; and

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B = foreign exchange conversion rate, expressed in local currency of the foreign country per United States Dollar (using, as the applicable foreign exchange rate, the spot purchase rate published in the *Financial Times* on the last Business Day of each Calendar Quarter in which any payment is due and payable or any other mutually agreed upon source, for such Calendar Quarter).

(b)Taxes. Company is responsible for all taxes, duties, import duties, assessments, and other governmental charges, however designated, which are now or hereafter imposed by any authority on Company only to the extent Company is the taxpayer according to Applicable Law. The existence of duties or import duties payable by TG according to Applicable Law (for the avoidance of doubt, not including any withholding taxes payable by TG) shall not increase accordingly the amounts payable by Company unless the local regulation governing any such duties or import duties expressly allows the taxpayer to pass this cost on to the Company, in which case the sum payable by Company to TG pursuant to the terms of this Agreement shall be increased by such obligation.

Without prejudice to the Gross-Up Mechanism established (and defined) below, if Applicable Laws require that Taxes be deducted and withheld from a payment made pursuant to this Article 8:

(i) Company shall (A) deduct those Taxes in the amount required by Applicable Laws from the payment; (B) pay the Taxes to the proper taxing authority; and (C) send evidence of the obligation together with proof of payment to TG within thirty (30) days following that payment, and

(ii) the Parties shall perform all acts (including by executing all appropriate documents and/or filing all appropriate tax returns, applications, filing or information with any competent governmental authority) so as to enable the other Party to take advantage of any applicable double taxation agreement or treaty or to otherwise secure any applicable exemption

from or reduction in withholding Taxes, including the delivery of any prescribed forms necessary (or which have been requested by a governmental authority) to reduce the applicable rate of withholding or relieve the obligation to withhold such tax or any other information or documentation requested by a Party to comply with its tax obligations (for example, and non-exclusively, a tax resident certificate within the meaning of the applicable double tax treaty issued by the relevant US tax authority confirming that TG is tax resident in the US within the meaning of the Spain-US tax treaty, the "*DTT Residence Certificate*") and such shall be provided on an annual basis before the due date of the first payment under this Agreement for such Calendar Year, including but not limited to the form attached as Schedule 8.3.6.

Any deductions or withholding for taxes that Company is required by Applicable Law to deduct or withhold on remittance of payments to TG pursuant to the terms of this Agreement shall be paid forthwith by Company to the appropriate taxing authority, and the sum payable by Company to TG pursuant to the terms of this Agreement shall be increased as necessary so that after any required withholding or the making of all required deductions (including deductions or withholdings applicable to additional sums payable under this provision), TG receives an amount equal to the sum which would have been received by TG had no such deduction or withholding been made (the "*Gross-Up Mechanism*"). Where Taxes have been deducted or withheld by Company from a payment made pursuant to this Article 8, TG will be required to pursue

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commercially reasonable actions and tax filings according to Applicable Law to obtain and claim any available refund, relief, exemption, tax credit, tax benefit or others in order to eliminate any double taxation and/or to recover (or credit or refund) the taxes withheld and/or paid (in full or to the maximum extent permitted under Applicable Law) as promptly as possible in the US, Spain or elsewhere including but not limited to the applicable tax return corresponding to the fiscal year where such withholding or deduction has taken place. The maximum amount that is recoverable, refundable, creditable, or that otherwise could be claimed and/or received according to Applicable Law (including by any Affiliate of TG, e.g. under any group taxation regime) as a result of the application of those measures to eliminate any double taxation

and/or to recover (or credit or refund) the Taxes withheld will be directly paid in cash to Company (or as an offset to any amounts due from Company to TG under this Agreement, at TG's election) the day after the applicable tax return of the fiscal year where such relief has been used or claimed, is or should have been filed according to Applicable Law, even if it is not fully recovered, refunded, credited or otherwise received in that tax return but can potentially be in the future. The amounts recovered and to be paid to Company will be subsequently adjusted in case that they differ from the final amount resulting from an assessment received by any taxing authority and/or administrative court or courts of justice where the assessment, resolution and/or in general a decision reached by any of those bodies is final and no further appeal can be made.

The Gross-Up Mechanism will not apply where TG ceases to be tax resident in the United States. The Gross-Up shall be limited to [***] of the amounts of taxes withheld or deducted from any payment resulting from this Agreement if there is a change in the Applicable Law that modifies the withholding tax rules relevant to this Agreement applicable at the date of signing and/or in the relevant provisions of the Spain-US tax treaty applicable to this Agreement at the date of signing (modifications that do not impact the application of withholding tax or the amount of withholding tax to be applied (if any) shall not be relevant for the purpose of this sentence).

TG undertakes to (i) use best efforts to obtain a DTT Residence Certificate as soon as possible following the Effective Date, (ii) forward any such DTT Residence Certificate immediately after receipt to the Company and (iii) deliver the confirmations and documentation included as template in Schedule 8.3.6 properly completed and signed ("*TG Residence Confirmation*") immediately after the signing of this Agreement and before the first payment under this Agreement from the Company to TG.

Where TG does not provide Company with a proper DTT Residence Certificate and the documents in Schedule 8.3.6 of this Agreement, on an annual basis (understood as each year and referring to the specific fiscal year where payments under this Agreement are made and in relation to the TG Residence Confirmation in any case before the first payment to be made by the Company under this Agreement), or where such information and/or documents, where applicable, are missing, false, incorrect, unclear, inconclusive or inaccurate, any Loss (including for the avoidance of doubt any Tax, Withholding Tax delay payment interest, surcharges or penalties generated and/or applicable) of the Company (or the wider Neuraxpharm Group) directly caused, generated upon or occurring as a result of any such non-provision or missing, false, incorrect, unclear, inconclusive or inaccurate

information and/or documentation, shall be indemnified by TG to Company and TG will hold Company harmless from any such Loss.

In the case such Loss is a Tax (and related additions, interest or late payment penalties) that arises as a result of a Tax audit assessment or any other (tax) assessment deriving from a verification

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procedure or otherwise by any governmental authority (including any taxing authority or (tax) courts), the amount to be paid by TG to Company will be the final amount resulting from any assessment received by any such governmental authority if and when such assessment is final cannot be further appealed. Without prejudice to the above, TG will assume and pay the corresponding amounts resulting from the assessment as soon as those amounts are required to be paid by such relevant governmental authority.

For the purposes of this Section8.3.6 and Section11.2.5(b), any reference to TG shall mean and oblige each of TG Therapeutics, Inc. and TG Biologics, Inc. individually, and each of them shall individually be obliged to in particular provide the documentation required to be provided by them hereunder.

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

Subject to paragraph b) above of Section 8.3.6), in the case the result of any assessment, proposed assessment, or other claims by any Governmental Authorities with respect to Taxes is due to missing, false, incorrect or inaccurate information provided, Taxes will be borne by the relevant taxpayer according to Applicable Law, including penalties, interest or additions to Tax attributable thereto.

(d)Currency Restrictions. If any restrictions on the transfer of currency exist in any country in which Products are sold that prevent Company

from making royalty payments thereon in United States Dollars, Company shall make royalty payments on the sales in such country in the local currency by deposit in a local bank or other depository designated in writing by TG (or, in the absence of such designation, at a local bank or other depository selected by Company and identified by Company by written notice to TG).

9. TREATMENT OF CONFIDENTIAL INFORMATION; PUBLICITY

9.1 Confidentiality.

9.1.1 **Confidentiality Obligations. TG and Company each recognize that the other Party's Confidential Information and Proprietary Materials constitute highly valuable assets of such other Party. TG and Company each agrees that, (a) subject to Section 9.1.2, during the Term and for an additional ten (10) years after termination or expiration of this Agreement it will not disclose, and will cause its Affiliates, Sublicensees, and Distributors not to disclose whether directly or indirectly, in any manner whatsoever, any Confidential Information or Proprietary Materials of the other Party, and (b) it will not use, and will cause its Affiliates, Sublicensees, and Distributors not to use, any Confidential Information or Proprietary Materials of the other Party, without the prior written consent of the Disclosing Party, except as expressly permitted hereunder.**

9.1.2 **Limited Disclosure. TG and Company each agrees that disclosure of its Confidential Information or any transfer of its Proprietary Materials may be made by the other Party on a need-to-know basis to any employee, consultant, or Affiliate of such other Party or, to**

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the extent the receiving Party is Company, to any Third Party subcontractor engaged by Company pursuant to Section 2.2, in each case solely to the extent reasonably necessary to enable such other Party to exercise its rights or to carry out its responsibilities under this Agreement; provided, that, any such disclosure or transfer shall only be made to Persons who are bound by written obligations no less stringent than those obligations described in Section 9.1.3. TG and Company each further agrees that the other Party may disclose its Confidential Information (a) on a need-to-know basis to such other Party's legal and

financial advisors; (b) as reasonably necessary in connection with an actual or potential (i) permitted sublicense of such Party's rights hereunder, (ii) debt or equity financing of such other Party or (iii) acquisition, consolidation, share exchange, or other similar transaction involving such Party and any Third Party (including, without limitation, a Change of Control of TG); (c) to the extent the receiving Party is Company, to any Third Party that is or may be engaged by Company to perform services in connection with the Commercialization of the Product as necessary to enable such Third Party to perform such services; (d) to the extent the receiving Party is TG, to LFB (or, as applicable, Dr. Hadam under the Hadam License); (e) as reasonably necessary to make Regulatory Filings with respect to the Product under this Agreement or to respond to any inquiry made by any Regulatory Authority with respect to the Product and to prosecute or maintain Patent Rights, or to file, prosecute, or defend litigation related to Patent Rights, in accordance with this Agreement; (f) as required by Applicable Laws (which shall be determined by the Disclosing Party in its reasonable discretion, and including, without limitation, 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); provided, that, in the case of any disclosure under this clause (f), the Disclosing Party shall (i) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure and (ii) if requested by the Disclosing Party, cooperate in all reasonable respects with the Disclosing Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the Disclosing Party's expense; provided, that, any such disclosure or transfer according to (a) – (d) above shall only be made to Persons who are bound by obligations no less stringent than those obligations described in Section 9.1.3.

9.1.3 **Employees and Consultants. TG and Company each hereby covenants and agrees that all of its employees and consultants, and all of the employees and consultants of its Affiliates, who have access to Confidential Information or Proprietary Materials of the other Party will, prior to having such access, be bound by written obligations to maintain such Confidential Information or Proprietary Materials in confidence that are no less stringent than those confidentiality and non-use provisions contained in this Agreement. Each Party agrees to use, and to cause its Affiliates to use, reasonable efforts to enforce such obligations and to prohibit its employees and consultants from using such information except as expressly permitted hereunder. Each Party will be liable to the other Party for any disclosure or misuse by**

its employees or consultants of Confidential Information or Proprietary Materials of the other Party.

9.1.4 Trade Secrets. Notwithstanding any provision to the contrary, to the extent that any of TG's Confidential Information and/or Proprietary Materials constitutes a "trade secret" under Applicable Law, the confidentiality and non-use obligations under this Agreement shall continue for so long as such Confidential Information and/or Proprietary Materials constitutes a "trade secret" under Applicable Law. This Agreement is intended to be in addition to and not in lieu of common law or statutory protections provided for trade secrets.

9.2 Publicity. Notwithstanding anything to the contrary in Section 9.1, the Parties, upon the execution of this Agreement, shall jointly issue a press release with respect to this Agreement to be reasonably agreed by the Parties in substantially the form attached hereto as Exhibit C, and either Party may make subsequent public disclosure of the contents of such press release without further approval of the other Party. Subject to the foregoing, except as required by Applicable Laws (including those relating to disclosure of material information to investors), neither Party shall issue a press or news release or make any similar public announcement (it being understood that publication in scientific journals, presentation at scientific conferences and meetings, and the like are intended to be covered by Section 9.4 and not subject to this Section 9.2) related to the terms or existence of this Agreement, any Company Development Activities, or the Commercialization of Product by or on behalf of Company, without the prior written consent of the other Party; provided, however, that either Party may make such a disclosure (a) to the extent required by Applicable Laws (including 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), or (b) to any investors, prospective investors, lenders, and other potential financing sources who are obligated to keep such information confidential. Once any press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. For the avoidance of doubt, nothing herein shall restrict TG's ability to issue a

press or news release to make any similar public announcements relating to its Development activities or its Commercialization activities of the Product.

9.3 **No Use of Name. Neither Party shall use the name of the other Party in any Promotional Materials or advertising without the prior express written permission of the other Party.**

9.4 **Publications and Presentations. Company shall not publish or present any results (the "*Results*") of any Global Development Activities and/or Company Development Activities, without the prior written consent of TG in its sole discretion. Without limiting the generality of any provision in this Agreement, in the event that Company attends an international conference with attendees from both the Territory and the Excluded Territory, including, without limitation, ECTRIMS, EAN, AAN, and ACTRIMS, Company shall cooperate with TG regarding a coordinated approach to any and all such conferences, including with respect to a reasonable allocation of any associated costs.**

10. INTELLECTUAL PROPERTY RIGHTS

10.1 **Ownership. As between the Parties, TG (and/or LFB, as applicable) is, and shall be, the sole and exclusive owner of all right, title, and interest in and to any and all Licensed Technology and Licensed Patent Rights. Additionally, TG (and/or LFB, as applicable, in accordance with the LFB License) shall be the sole and exclusive owner of all Arising IP, and Company shall promptly notify TG of the development of any such Arising IP (including that, upon TG's request, Company shall provide to TG all data and specifications concerning such Arising IP). Company hereby assigns, and shall cause its Affiliates, Sublicensees, and Distributors and their respective personnel to assign, to TG and/or LFB, as applicable, all right, title, and interest, in and to all Arising IP.**

10.2 **Filing, Prosecution, and Maintenance. TG and/or LFB, as applicable, shall have the sole right (but not obligation) to prepare and file patent applications with respect to, and to prosecute and maintain, at its sole cost, expense, and discretion, and using patent counsel or agents of its choice, all Licensed Patent Rights and patentable subject matter included in the Arising IP**

throughout the Territory, and to otherwise seek protection of any Licensed Technology or other Arising IP under applicable intellectual property laws. Company shall cooperate with and assist, and shall cause its Affiliates, Sublicensees, and Distributors and their respective personnel to cooperate with and assist, TG and/or LFB in all reasonable respects, in connection with TG's and LFB's activities under this Section 10.2.

10.3 **Information and Cooperation. Company hereby agrees to cooperate with TG and LFB in connection with the filing, prosecution, and maintenance of Patent Rights under this Agreement, including through the prompt execution and delivery of documents and instruments as may reasonably be required in connection therewith, including, without limitation, assignments. Without limiting the foregoing, TG shall (a) promptly provide Company with copies of all patent applications filed with respect to the Licensed Patents in the Territory, to the extent such Patent Rights Cover the Product in the Field, and other material submissions and correspondence with applicable patent offices, in sufficient time to allow for Company to review and comment; (b) provide Company and its patent counsel with an opportunity to consult with TG and its patent counsel regarding the filing and contents of any such application, amendment, submission or response; and (c) take into consideration in good faith the advice and suggestions of Company and its patent counsel in connection with such filing.**

10.4 **Interference, Opposition, Reexamination, and Reissue.**

10.4.1 **Notice. Not more than [***] ([***]) [***] following the discovery by either Party of any request for, or the filing or declaration of, any interference, opposition, or reexamination proceeding with respect to any Licensed Patent Rights in the Territory, the discovering or determining Party shall notify the other Party of such event.**

10.4.2 **Responsibility and Cooperation. TG and/or LFB, as applicable, shall have the sole right and responsibility, at its own expense, to defend or prosecute any such interference, opposition, reexamination, or reissue. Company shall cooperate and provide TG and/or LFB with any information or assistance that TG and/or LFB may reasonably request with respect to any course of action taken under this Section 10.4.2. TG shall (a) keep Company reasonably informed of all developments in such interference, opposition, reexamination, or reissue in the Territory, to the extent that the applicable Licensed Patent Right Covers the Product in the Field, including to the extent permissible, the status of any settlement negotiations and the terms of any offer related thereto**

and (b) provide to Company copies of all submissions or agreements arising in connection with such proceeding sufficiently in advance of their filing or due date as to give Company sufficient time to comment thereon, and TG shall give good faith consideration to Company's comments; provided, however, that TG's obligation to provide such copies with sufficient time to comment thereon shall be subject to TG's good faith determination that the time required to so provide and await comments would not materially impair the availability of rights or remedies, or increase exposure, in connection with such interference, opposition, reexamination, or reissue.

10.5 **Enforcement and Defense.**

10.5.1 **Third Party Infringement.**

(a)Notice. In the event either Party becomes aware of any suspected infringement or misappropriation of any Licensed Patent Rights that Covers the Development or Commercialization of the Compound or the Product in the Field in the Territory (each, an "*Infringement*"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "*Infringement Notice*").

(b)TG Right to Enforce. TG and/or LFB, as applicable, shall have the sole right, but not the obligation, to address any such Infringement in the Territory by taking reasonable steps, which may include the institution of legal proceedings or other actions (each, an "*Action*"), and to compromise or settle such Action; provided, that, (i) TG shall keep Company reasonably informed about such Action, and (ii) Company shall provide reasonable cooperation to TG and/or LFB in connection with such Action. TG and LFB shall incur no liability to Company as a consequence of such Action or any unfavorable decision resulting therefrom, including any decision holding any such claim invalid, not infringed, or unenforceable. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by TG and/or LFB, as applicable.

(c)Right to Representation. Company shall have the right to participate and be represented by counsel that it selects, in any Action instituted by TG or LFB under Section 10.5.1(b). If TG and/or LFB lacks

standing to initiate an Action, and Company has standing to initiate such Action, then TG and/or LFB may name Company as plaintiff in such Action or may require Company to initiate such Action at TG's expense.

(d)Cooperation. In any Action instituted under this Section 10.5.1, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of TG and/or LFB, Company shall join such Action and shall be represented using counsel of its own choice, at TG's or LFB's expense.

(e)Allocation of Proceeds. Any amounts recovered by TG in connection with its activities under this Section 10.5.1 with respect to any Infringement, whether by settlement or judgment, shall, after reimbursing Company and TG for their respective reasonable out-of-pocket expenses incurred in pursuing such Action and obtaining such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses) be retained by TG.

10.5.2 **Defense of Claims.**

(a)Notice. In the event that any action, suit, or proceeding is brought against either Party or any Affiliate of either Party or any Sublicensee or Distributor of Company alleging the infringement of the Technology or Patent Rights or any other intellectual property of a Third Party by reason of or the Development or Commercialization, including the Manufacture, use, or sale, of the Compound or Product, by or on behalf of Company, its Affiliates, Sublicensees, or Distributors (such action, suit, or proceeding, a "*Defensive Action*"), such Party shall notify the other Party within [***] ([***]) [***] of the earlier of (i) receipt of service of process in such

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Defensive Action, or (ii) the date such Party becomes aware that such Defensive Action has been instituted and the Parties shall meet as soon as possible to discuss the overall strategy for defense of such matter.

(b)Prosecution of Defensive Actions in the Territory. TG and/or LFB, as applicable, and only to the extent permissible under Applicable Law, shall have the sole right, but not the obligation, to institute and/or control such Defensive Action in its own name and at its sole expense; and in such case, Company and/or any of its

Affiliates shall have the right to separate counsel at its own expense in any such Defensive Action, and Company shall cooperate with TG and/or LFB in all reasonable respects in any such Defensive Action. Without limiting the generality of the foregoing, solely upon TG's request, Company shall defend any Defensive Action in its own name and at its sole expense; and in such case TG and/or any of its Affiliates shall have the right to separate counsel at its own expense in any such Defensive Action, and TG shall cooperate with Company in all reasonable respects in any such Defensive Action.

(c)Cooperation. Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party including all documents filed in any litigation. In no event shall either Party settle or otherwise resolve any such action, suit, or proceeding brought against the other Party or any of its Affiliates or sublicensees without the other Party's prior written consent (not to be unreasonably withheld, conditioned, or delayed).

10.5.3 Patent Term Restoration. The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Licensed Patent Rights and/or Arising IP. Such cooperation shall include diligently and timely conferring and coordinating with respect to such matters to ensure compliance with applicable filing deadlines and agreeing on procedures to be followed by the Parties to ensure such compliance. In the event that elections with respect to obtaining such patent term restoration are to be made, TG and/or LFB shall have the right to make the election with respect to Licensed Patent Rights and/or Arising IP. The Parties agree that for those cases where TG and/or LFB initially agree not to obtain patent term restoration and/or supplemental protection certificates, Company shall nonetheless have the right to overrule such decision, and as consequence patent term restoration and/or supplemental protection certificates shall be obtained at the sole cost and expense of Company.

10.6 Trademark Prosecution and Registration. TG shall control the registration of the Licensed Trademark in the Territory. TG shall have the sole right (but not obligation) to take any actions as are required to continue and maintain in full force and effect and enforce and defend the Licensed Trademark and registrations thereof, against infringement and misappropriation in the Territory, and shall be solely responsible for all expenses incurred in connection therewith. Upon TG's request,

Company shall reasonably cooperate and assist with the activities contemplated by this Section 10.6.

11. TERM AND TERMINATION

11.1 **Term. This Agreement shall commence on the Effective Date and shall continue in full force and effect until terminated pursuant to Section 11.2 (the "*Term*").**

11.2 **Termination. This Agreement may be terminated as follows:**

11.2.1 **TG Rights to Terminate for Challenge. Except to the extent the following is unenforceable under the Applicable Laws of a particular jurisdiction where a patent application within the Licensed Patent Rights and/or the Arising IP is pending or a patent within the Licensed Patent Rights and/or the Arising IP is issued, TG may terminate this Agreement immediately upon written notice to Company in the event that Company or any of its Affiliates, Sublicensees, or Distributors Challenges any Licensed Patent Rights and/or Arising IP or assists a Third Party in initiating a Challenge of any Licensed Patent Rights and/or Arising IP.**

11.2.2 **Termination for Breach. Either Party may terminate this Agreement, effective immediately upon written notice to the other Party, for a material breach by the other Party of any term of this Agreement and/or the Supply Agreement that remains uncured [***] ([***]) [***] after the non-breaching Party first gives written notice to the other Party of such breach and its intent to terminate this Agreement if such breach is not cured; provided, however, that the cure period for breach of any payment obligation shall be [***] ([***]) [***].**

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

11.2.4 **Termination for Failure to Achieve [***] of Sales Target. If LFB has sent or has threatened in writing**

to TG to send to TG a termination notice pursuant to section 5.5.2 para. 2 of the LFB License (i.e., based on the grounds that TG failed to achieve [***] ([***]) of the sales targets applicable under the LFB License for [***] ([***]) consecutive commercial years), then TG shall have the right to terminate this Agreement with respect to country(-ies) within the Territory where [***] of the Sales Targets for the Product in the Field in such country were not achieved and in relation to which LFB has terminated or threatened in writing to terminate the LFB License; provided, however, that (a) TG shall provide [***] ([***]) [***] prior written notice of termination, and, if during such [***] ([***]) [***] period Company achieves [***] of the Sales Target for such [***] ([***]) [***] period, then Company shall be deemed to have cured the breach and the termination will be null and void, (b) TG shall, upon the effective date of such termination, purchase back the Product stock held by Company at the price paid by Company for the Product under the Supply Agreement, and (c) such termination right shall not apply if the failure to achieve the Sales Target in such country is due to a Product supply failure not attributable to Company, provided that Company has satisfied its safety stock obligations set forth in the Supply Agreement and has exhausted its safety stock of the Product. For the purpose of this Section 11.2.4, Company means Company, and where applicable, its Affiliates, Sublicensees, and Distributors.

11.2.5 **Termination Following Change of Control; the Buy-Back Option.**

(a)Upon the first consummation of a Change of Control of TG following the Effective Date, TG or its successor-in-interest shall have the right to terminate this

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Agreement immediately by providing Company with written notice of termination (the "*Buy-Back Option*"); provided, however, that:

(i)the Buy-Back Option may be exercised only in connection with the first occurrence of a Change of Control of TG and, for the avoidance of doubt, shall not apply in relation to any subsequent agreement pursuant to which TG or its successor-in-interest would reasonably expect to undergo a Change of Control (a "*CoC*

Agreement") and/or any other subsequent Change of Control in relation to TG or its successor-in-interest;

(ii)the applicable CoC Agreement is signed no later than [***];

(iii)the applicable Change of Control is consummated no later than [***];

(iv)notice of the exercise of the Buy-Back Option is given within [***] ([***]) [***] following the consummation of the applicable Change of Control;

(v)the Parties shall comply with the provisions of Schedule 11.2.5(a)(v) with respect to Company Employees;

(vi)TG or its successor-in-interest shall re-purchase supplies and Raw Materials in accordance with Section 11.4.4(g); and

(vii)TG or its successor-in-interest pays Company, as follows:

A.in the event TG or its successor-in-interest exercises the Buy-Back Option at any time on or prior to [***], an amount equal to [***] ([***]) the sum of any Upfront Payment and/or Milestone Payments made by Company to TG or its successor-in-interest as of the date of such exercise of the Buy-Back Option;

B.in the event TG or its successor-in-interest exercises the Buy-Back Option at any time after [***] but on or prior to [***] , an amount equal to [***] ([***]) the sum of any Upfront Payment and/or Milestone Payments made by Company to TG or its successor-in-interest as of the date of such exercise of the Buy-Back Option;

C.in the event TG or its successor-in-interest exercises the Buy-Back Option at any time after [***]but on or prior to [***] (or, should the relevant Change of Control be consummated less than [***] ([***]) [***] prior to [***], on or prior to the date which is [***] ([***]) [***] following the consummation of the applicable Change of Control), an amount equal to [***] ([***]) the sum of any Upfront Payment and/or Milestone Payments made by Company to TG or its successor-in-interest as of the date of such exercise of the Buy-Back Option.

(b)Taxes. Without prejudice to the Buy-Back Gross-Up Mechanism established (and defined) below, if Applicable Laws require that Taxes be deducted and withheld from a payment made pursuant to this Section 11.2.5, then:

(i)TG shall (A) deduct those Taxes in the amount required by Applicable Laws from the payment; (B) pay the Taxes to the proper taxing authority; and (C) send

evidence of the obligation together with proof of payment to Company within [***] ([***]) [***] following that payment, and

(ii)the Parties shall perform all acts (including by executing all appropriate documents and/or filing all appropriate tax returns, applications, filing or information with any competent governmental authority) so as to enable the other Party to take advantage of any applicable double taxation agreement or treaty or to otherwise secure any applicable exemption from or reduction in withholding Taxes, including the delivery of any prescribed forms necessary (or has been requested by a governmental authority) to reduce the applicable rate of withholding or relieve the obligation to withhold such tax or any other information or documentation requested by a Party to comply with its tax obligations (for example, and non-exclusively, a tax resident certificate within the meaning of the applicable double tax treaty) and such shall be provided before the due date of payment pursuant to this Section 11.2.5.

Any deductions or withholding for taxes that TG is required by Applicable Law to deduct or withhold on remittance of payments to Company pursuant to the terms of this Agreement shall be paid forthwith by TG to the appropriate taxing authority, and the sum payable by TG to Company pursuant to the terms of this Section 11.2.5 shall be increased as necessary so that after any required withholding or the making of all required deductions (including deductions or withholdings applicable to additional sums payable under this provision), Company receives an amount equal to the sum which would have been received by Company had no such deduction or withholding been made (the "*Buy-Back Gross-Up Mechanism*"). Where Taxes have been deducted or withheld by TG from a payment made pursuant to this Section 11.2.5, Company will be required to pursue commercially reasonable actions and tax filings according to Applicable Law to obtain and claim any available refund, relief, exemption, tax credit, tax benefit or others in order to eliminate any double taxation and/or to

recover (or credit or refund) the taxes paid withheld and/or paid (in full or to the maximum extent permitted under Applicable Law) as promptly as possible in the US, Spain or elsewhere including but not limited to the applicable tax return corresponding to the fiscal year where such withholding or deduction has taken place. The maximum amount that is recoverable, refundable, creditable, or that otherwise could be claimed and /or received according to Applicable Law (including by any Affiliate of TG, e.g. under any group taxation regime) as a result of the application of those measures to eliminate any double taxation and/or to recover (credit or refund) the Taxes withheld will be directly paid in cash to TG the day after the applicable tax return of the fiscal year where such relief has been used, is or should have been filed according to Applicable Law, even if it is not fully recovered, refunded, credited or otherwise received in that tax return but can potentially be in the future. The amounts recovered and to be paid to TG will be subsequently adjusted in case that they differ from the final amount resulting from an assessment received by any taxing authority and/or administrative court or courts of justice where the assessment, resolution and/or in general a decision reached by any of those bodies is final and no further appeal can be made.

The Buy-Back Gross-Up Mechanism will not apply where Company ceases to be tax resident in Spain.

The Buy-Back Gross-Up shall be limited to the [***] of the amounts of taxes withheld or deducted from any payment resulting from this Agreement if there is a change in the Applicable Law that modifies the withholding tax rules relevant to this Agreement applicable at the date of signing

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and/or in the relevant provisions of the Spain-US tax treaty applicable to this Agreement at the date of signing (modifications that do not impact the application of withholding tax or the amount of withholding tax to be applied (if any) shall not be relevant for the purpose of this sentence).

11.3 **Commercial License in Bankruptcy Scenario.**

11.3.1 **All rights and licenses now or hereafter granted under or pursuant to any section of this Agreement, including, inter alia, Section 2, are and will**

otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "*Bankruptcy Code*"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code.

11.3.2 **Company, as licensee of such rights under this Agreement, shall have all rights, elections, and protections under the Bankruptcy Code and all other applicable bankruptcy, insolvency, and similar laws with respect to this Agreement and the subject matter hereof. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.**

11.4 **Consequences of Termination of Agreement. In the event of the termination of this Agreement pursuant to Section 11.2, the following provisions shall apply, as applicable, except as TG agrees otherwise in its sole discretion for the sake of patient safety and otherwise orderly transition from Company to TG as contemplated by this Section 11.4.**

11.4.1 **All licenses and rights granted by TG to Company, including all licenses granted to Company pursuant to Section 2.1, shall immediately terminate. Any Sublicense in effect immediately prior to the termination of this Agreement shall automatically terminate, unless TG determines, in its sole discretion, to maintain such Sublicense, in which case, Company shall assign to TG such Sublicense and all rights thereunder, provided that (a) Company shall remain responsible and liable, in all respects, for all obligations and liabilities arising thereunder prior to such assignment, and (b) each such Sublicensee shall take all steps and execute all documents that TG reasonably requires in connection with its assumption of such Sublicense.**

11.4.2 **Company shall cease to use the Licensed Trademark and any Marketing Authorization obtained in accordance with this Agreement and shall promptly transfer such Marketing Authorizations and/or orphan drug designations to TG at no cost for TG.**

11.4.3 **Company shall cease to conduct any activity related to the Development and/or Commercialization of the Product in the Field in the Territory.**

11.4.4 **Promptly following the termination of this Agreement, Company shall promptly (and in any event within thirty ([***]) [***] of termination of this Agreement, or such other period of time if required under Applicable Law, except as required to enable Company to exercise its rights during the sell-off period contemplated**

by Section 11.4.4(g)(ii) solely during such sell-off period, as applicable):

(a)transfer to TG, and cause its Affiliates, Sublicensees, and Distributors to transfer to TG, all of their respective right, title and interest in all Drug Approval Applications, Marketing Authorizations, Regulatory Approvals, and any other Regulatory Filings

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then in any of their respective names, or otherwise under their Control, applicable to the Compound and/or Product in the Field in the Territory, if any, and all Confidential Information Controlled by Company as of the date of termination relied on by such Drug Approval Applications, Marketing Authorizations, Regulatory Approvals, and/or other Regulatory Filings. Until the transfer of any such Marketing Authorizations and/or Regulatory Approvals is complete, then, in each country in the Territory, as applicable, Company hereby appoints, and shall appoint, TG or its designee as its exclusive distributor of the Product in such country, with the right to appoint sub-distributors, to the fullest extent permissible under Applicable Law;

(b)notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer;

(c)provide TG with copies of all correspondence between Company and such Regulatory Authorities relating to such Drug Approval Applications, Marketing Authorizations, Regulatory Approvals, and/or other Regulatory Filings;

(d)unless expressly prohibited by any Regulatory Authority, transfer sponsorship and control to TG of all Clinical Trials of the Product in the Field in the Territory being conducted by or on behalf of Company as of the effective date of termination and, upon TG's request, continue to conduct such Clinical Trials after the effective date of termination to enable such transfer to be completed without interruption of any such Clinical Trial for up to [***] ([***]) [***] from the effective date of termination, which such conduct shall be at TG's cost and direction (except that Company will bear the costs if this Agreement is terminated by TG in accordance with Section 11.2.2);

(e)cooperate with TG, cause its Affiliates to cooperate with TG, and use commercially reasonable efforts to require any Third Party with which Company has an agreement with respect to the conduct of Clinical Trials for the Product (including agreements with contract research organizations, clinical sites, and investigators), to cooperate with TG in order to accomplish the transfer to TG of similar rights as held by Company under its agreements with such Third Parties;

(f)provide TG with copies of all reports, Company Data, records, materials, and documentation generated or obtained by Company or its Affiliates, and all Promotional Materials used by Company, pursuant to this Agreement that relate to the Product in the Field in the Territory, and hereby assigns, transfers, and conveys, and shall assign, transfer, and convey, to TG all right, title, and interest in and to the Company Data, results, and any other information in any Drug Approval Applications, Marketing Authorizations, Regulatory Approvals, and/or other Regulatory Filings applicable to the Commercialization of the Product in the Field in the Territory and all material aspects of Confidential Information Controlled by it as of the date relating to such Drug Approval Applications, Marketing Authorizations, Regulatory Approvals, and/or other Regulatory Filings for TG to use to seek Regulatory Approvals for the Product (whether in or outside the Territory, and whether in or outside the Field);

(g)together with TG, handle inventory of Compound, Product, and Raw Materials, and binding portions of forecasts under the Supply Agreement, as follows:

(i)[***]; or

(ii)in the event of a termination of this Agreement for any reason other than in accordance with Section 11.2.5, then, in TG's sole discretion, either:

A. [***]; or

B. [***]; and,

in addition, with respect to Drug Substance, in both scenarios of either (A) and (B), as regards (y) Drug Substance and/or Raw Materials already owned by

Company, return to TG (at Company's election, by way of sale or against issuance of a credit note by TG) such portion of such Drug Substance and/or Raw Materials as TG can – for the avoidance of doubt and without limitation, taking into account its current stock levels, binding forecasts, and shelf life of such Drug Substance and/or Raw Materials – reasonably be expected to use to satisfy existing or future demand and (z) Drug Substance subject to binding forecasts in accordance with the Supply Agreement, TG shall take over such [***];

(h)provide TG with copies of all reports and data generated or obtained by Company or its Affiliates pursuant to this Agreement that relate to the Product in the Field in the Territory; and

(i)if by virtue of the Transfer Regulations and the termination of this Agreement (whether in whole or in part) for whatever reason, any employment or any liability regarding the employment of any Company Employee shall transfer to (or be alleged to transfer to) TG and/or any New Commercialization Provider (a "*Transfer Claimant*"), TG may terminate (or procure that any New Commercialization Provider may terminate) the employment of such Transfer Claimant and, provided that: (a) TG terminates the employment of a Transfer Claimant without undue delay following the later of the transfer date or the allegation of such transfer by a Transfer Claimant and (b) the transfer of employment of a Transfer Claimant is not caused by TG or the New Commercialization Provider making offers of employment to any Company Employees in the same jurisdiction, Company shall indemnify TG and the New Commercialization Partner in full for and against all reasonable Losses (including reasonable costs for severance pay, it being understood and agreed that any offering of severance to a Transfer Claimant requires the Company's consent which shall not be unreasonably withheld or delayed) incurred or suffered by TG or any New Commercialization Provider arising out of or in connection with the employment and/or termination of such Transfer Claimant (save that this indemnity shall not cover the costs of employing any Transferring Employee for any full days on which the Transferring Employee actively provides work or services to TG (as determined by TG acting reasonably)). For the avoidance of doubt: If TG does not terminate the employment of a Transfer Claimant without undue delay following the later of the transfer date or the allegation of such transfer by a Transfer Claimant, TG shall be solely liable for any Loss with regard the employment of the Transfer Claimant or its termination. This clause shall not apply to a termination of this Agreement pursuant to the Buy-Back Option.

Additionally, promptly following the termination of this Agreement, Company shall enter into good faith negotiations with TG and agree upon and implement a plan for the orderly transition

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of Company Development Activities and Commercialization from Company to TG in a manner consistent with Applicable Laws and standards of ethical conduct of human Clinical Trials and will seek to replace all Company personnel engaged in any such Development or Commercialization activities, in each case, as promptly as practicable. In connection therewith, Company hereby assigns, transfers, and conveys, and shall assign, transfer, and convey, to TG all right, title, and interest in and to any intellectual property (including, without limitation, Company Data) Controlled by Company and/or its Affiliates that is necessary or useful for the Development and/or Commercialization of the Product in the Field in the Territory.

Notwithstanding any provision to the contrary of this Agreement, upon termination of this Agreement, any information, Technology, and/or Proprietary Materials that arose following the Effective Date and under the performance of this Agreement that would otherwise be the Confidential Information of Company, is and shall be the Confidential Information of TG as of the effective date of termination.

11.4.5 **Each Party shall promptly return all Confidential Information and Proprietary Materials of the other Party that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.**

11.4.6 **Company shall promptly return to TG all raw data and results generated in each Clinical Trial conducted in connection with the Product in the Territory (whether provided by TG to Company as Licensed Technology or Company Data).**

11.5 **Surviving Provisions. Termination of this Agreement for any reason shall be without prejudice to:**

(a) **Survival of rights specifically stated in this Agreement to survive, including without limitation as**

set forth in Section 11.4;

(b) the rights and obligations of the Parties provided in Sections 2.1.2 (with respect to the license grant referred to therein, if applicable), 3.7, 8.3.3, 8.3.6, 9, 10.1, 10.5, 11.2.5, 11.3.2, 11.4, 11.5, 13, 14.1, and 14.3 (including all other Sections or Articles referenced in any such Section or Article), all of which shall survive such termination except as provided in this Article 11; and

(c) any other rights or remedies provided at law or equity which either Party may otherwise have, including all payment obligations that have accrued as of the effective date of termination.

12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations, Warranties, and Covenants. TG and Company each hereby represents, warrants, and covenants to the other, as of the Effective Date, as follows:

12.1.1 Organization. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

12.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or bylaws (or equivalent charter or organizational documents), (b) any agreement, instrument, or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any Applicable Laws, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

12.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions.

12.1.4 No Inconsistent Obligation. Neither it nor its assets is under any obligation, contractual or otherwise, to any Person that conflicts with or is

inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

12.1.5 **No Government Authorization Required. No government authorization, consent, approval, license, exemption of, or filing or registration with any court or governmental department, commission, board, bureau, agency, or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement.**

12.1.6 **Compliance. Each Party shall comply with all Applicable Laws in connection with its performance of the activities contemplated by this Agreement.**

12.2 **Additional Representations and Warranties of TG. TG further represents and warrants to Company, as of the Effective Date, as follows:**

12.2.1 **Right to Grant License. TG has the right to grant the license and rights set forth in Section 2; provided, however, and notwithstanding Section 12.2.5, this Section 12.2.1 shall not be construed or deemed to be a representation or warranty regarding the infringement or other violation of the intellectual property rights of any Third Party.**

12.2.2 **Validity of IP Rights. All Licensed Patent Rights listed on Schedule 12.2.2(b), the Licensed Trademark listed on Schedule 12.2.2(c), and the LFB Background Patent Rights listed on Schedule 12.2.2(a) are existing and, to TG's Knowledge, no issued intellectual property rights which are part of the Licensed Patent Rights listed on Schedule 12.2.2(b), the Licensed Trademark listed on Schedule 12.2.2(c), and/or the LFB Background Patent Rights listed on Schedule 12.2.2(a) are invalid or unenforceable. To TG's Knowledge, the Licensed Technology is in existence, and available to be validly and enforceably used hereunder.**

12.2.3 **No Claims. There are no claims, judgments, or settlements against TG pending, or to TG's Knowledge, threatened, that invalidate or seek to invalidate the Licensed Patent Rights listed on Schedule**

12.2.2(b), the Licensed Trademark listed on Schedule 12.2.2(c), and/or the LFB Background Patent Rights listed on Schedule 12.2.2(a). There is no litigation pending against TG or any Affiliate of TG that alleges that any of TG's activities relating to the Compound or the Product have violated any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation).

12.2.4 **No License. TG has not previously entered into any agreement pursuant to which it granted a license with respect to the Product in the Field in the Territory, or under the Licensed Patent Rights, Licensed Technology or Licensed Trademark in the Field in the Territory, to any Affiliate or Third Party, which license grant remains in effect or which agreement has surviving license rights, or other surviving terms, that are inconsistent with the rights and licenses granted to Company under this Agreement.**

12.2.5 **Third Party Rights. To TG's Knowledge, no intellectual property rights owned or controlled by any Third Party will be infringed by the Development or Commercialization, by or on behalf of Company, of the Product in the Field in the Territory pursuant to this Agreement.**

12.2.6 **No Interference. To TG's Knowledge: (a) the Licensed Patent Rights and the LFB Background Patent Rights in the Territory are not the subject of any interference proceeding, and (b) there is no pending or threatened action, suit, proceeding, or claim by any Third Party challenging TG's and/or LFB's (as the case may be) ownership rights in, or the validity or scope of, the Licensed Patent Rights, Licensed Technology, Licensed Trademark, and/or the LFB Background Patent Rights in the Territory.**

12.2.7 **LFB License. TG has provided to Company, prior to the Effective Date, a complete and accurate copy of the LFB License. The LFB License is in full force and effect, and, to TG's Knowledge, neither party thereto is in material breach of the LFB License as of the Effective Date.**

12.3 **Additional Representations, Warranties, and Covenants of Company. Company further represents, warrants, and covenants to TG, as of the Effective Date (and, with respect to Section 12.3.6, during the Term), as follows:**

12.3.1 **No Claims. There is no litigation pending against Company or any Affiliate of Company that relates, directly or indirectly, to the subject matter of this Agreement and that alleges that any of Company's activities to be conducted relating to the Development and**

Commercialization of the Product in the Field in the Territory would violate any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation).

12.3.2 **Compliance with Applicable Laws**. **Company is in compliance with all Applicable Laws, and is not in default under or in violation of any Applicable Laws, that, in any case, would reasonably be expected to adversely affect the ability of Company to comply with and perform its obligations under this Agreement.**

12.3.3 **Financial and Human Resources**. **Company has all necessary financial and human resources to enter and perform all its commitments and obligations contained in the Agreement.**

12.3.4 **Competing Products**. **Neither Company nor any of its Affiliates nor any of the Other Permira Companies (a) conducts any activity, either on its own or with, for the benefit of, or sponsored by, any Third Party, that, in any case, involves the research, development or commercialization of any other anti CD 20 monoclonal antibody, or any compound that embodies or is derived from any anti CD 20 monoclonal antibody, whether in or outside the Field, or (b) otherwise conducts or is engaged in the research, development, and/or commercialization of any transgenically-derived chimeric monoclonal antibody for use in or outside the Field.**

12.3.5 **Other Permira Companies**. **Company shall not use any Other Permira Company to perform any activities, or have any role, with respect to Company's obligations under this Agreement or Company's Commercialization of the Product.**

12.3.6 **Debarment**. **Neither Company nor any of its Affiliates has been debarred or is subject to debarment, and neither Company nor any of its Affiliates will use in any capacity, in connection with its activities under this Agreement, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, and any rules or regulations promulgated thereunder, or who is the subject of a conviction described in such Section 306, or who is subject to any similar sanction of any Regulatory Authority or other governmental authority in the Territory. During the Term, Company will**

promptly inform TG in writing if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in such Section 306 or who is subject to any similar sanction, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending, or is threatened, relating to the debarment, conviction, or sanctions of it or any such Person performing hereunder.

12.3.7 **Compliance with Applicable ABC Laws. Without limiting the generality of Section 12.1.6, as of the Effective Date and throughout the Term: (a) none of its owners, directors, employees, contractors, representatives, agents, officers, or other members of its management (collectively, "*Company Persons*") are officials, officers, employees, agents, owners, directors, or representatives of any government, political party, state-owned entity, or public international organization, or instrumentality thereof, or candidate for public office (collectively, "*Officials*"); (b) Company shall immediately notify TG in writing if any Company Person becomes an Official; (c) Company and Company Persons have not caused and shall not cause TG or its Affiliates to be in violation of any applicable anti-corruption, anti-bribery, anti-kickback, anti-money laundering, anti-terrorist financing, anti-fraud, sanctions, embargo, export control, or other law, regulation, order, ordinance, mandatory rule, or other government or judicial decision (collectively, "*Applicable ABC Laws*"), including but not limited to the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "*FCPA*"); (d) Company and Company Persons have not promised, offered, authorized, provided, or accepted, and shall not promise, offer, authorize, provide, or accept, either directly or indirectly, money (including a bribe or kickback), gifts, entertainment, hospitalities, favors, or other things of value (collectively, a "*Payment*") to or from any Officials or any other person whether in the public or private sector, where such Payment would constitute a violation of any Applicable ABC Laws, including, without**

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limitation, the FCPA; (e) Company maintains and implements, and shall continue to maintain and implement, an effective compliance program, consisting of policies, procedures, training, and other measures and internal controls to cause Company and Company Persons to comply with all applicable anti-bribery/anti-corruption

laws and other Applicable ABC Laws and will provide copies of these policies and procedures upon request; (f) Company shall report any suspected or actual violation of any anti-bribery/anti-corruption laws or other Applicable ABC Laws in relation to this Agreement to TG immediately; (g) Company has provided and will continue to provide in good faith to TG and/or its representatives and advisors all due diligence documents and information of the character and type requested by TG; and (h) Company has not retained and shall not retain any third-party broker, agent, sub-representative, or other contractor to interact with Officials in the performance of this Agreement, unless such third party is vetted in advance to the satisfaction of TG. Company acknowledges and agrees that a violation of this Section 12.3.6 by Company or any Company Person constitutes a material breach of this Agreement, and, notwithstanding the provisions of Section 11.2.2, TG shall have the right to terminate this Agreement without any notice or cure period.

12.3.8 **Compliance with Applicable Trade Laws. Without limiting the generality of Sections 12.1.6 and 12.3.6, Company shall comply with all Applicable Laws controlling the export of certain commodities, technology, and technical data, including the Export Administration Regulations administered by the United States Department of Commerce and the International Traffic in Arms Regulations administered by the United States Department of State. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities, technology, and technical data to specified countries. Company hereby gives written assurance that it will comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations, and that it will indemnify and hold TG harmless for the consequences of any such violation. Additionally, Company agrees to comply with U.S. Sanctions administered by the Department of Treasury's Office of Foreign Assets Control and will ensure all of its Sublicensees and/or Distributors are appropriately screened against relevant global watchlists. Any positive screening results demonstrating a party's presence on a watchlist will be immediately reported to TG and no Product may be exported, re-exported, transferred, or transshipped to or through, sanctioned entities.**

12.3.9 **Company's Investigation and Non-Reliance. Company has been provided with access to the representatives and books and records of TG, including through an electronic data room, and other information (including the information necessary to determine whether to enter into this Agreement) that it has**

requested in connection with its investigation of the Compound, Product, and the transactions contemplated by this Agreement. Company is not relying, has not relied, and disclaims all reliance upon any statement, representation, or warranty (whether oral, written, express, or implied) made by TG or any of its Affiliates or representatives of any kind whatsoever, except as expressly set forth in Article 12. Except in the case of fraud, willful misconduct, or intentional misrepresentation, neither TG nor any of its Affiliates or representatives shall have any liability to Company or any of its Affiliates or representatives resulting from the use of any information, documents, or materials made available to Company (or its representatives), whether orally or in writing, in any confidential information memoranda, "data rooms," "virtual data rooms," management presentations, due diligence (whether or not received from TG or any of its Affiliates or representatives) in any form (including via discussion or

presentation) in expectation of the transactions contemplated by this Agreement. TG (and its Affiliates and representatives) is not making, directly or indirectly, any representation or warranty with respect to any estimates, projections, or forecasts involving the Product, including the likelihood of approval of any Drug Approval Application and/or the timing of any decision by the EMA or any other Regulatory Authority. Company acknowledges and agrees that there are inherent uncertainties in attempting to make such estimates, projections, and forecasts and that Company takes full responsibility for making its own evaluation of the adequacy and accuracy of any such estimates, projections, or forecasts (including the reasonableness of the assumptions underlying any such estimates, projections, or forecasts).

12.4 **Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT: THE LICENSED TECHNOLOGY, LICENSED PATENT RIGHTS, LFB BACKGROUND PATENT RIGHTS, AND LICENSED TRADEMARK, AS WELL AS THE COMPOUND AND PRODUCT, ARE BEING PROVIDED ON AN "AS IS, WHERE IS" BASIS; AND TG MAKES NO WARRANTY WITH RESPECT TO ANY COMPOUND, PRODUCT, TECHNOLOGY, PATENT RIGHTS, REGULATORY FILES, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MATTER OF THIS AGREEMENT, AND TG HEREBY**

DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT.

13. INDEMNIFICATION; INSURANCE

13.1 **Indemnification of TG by Company. Company shall indemnify, defend, and hold harmless TG, its Affiliates, their respective directors, officers, employees, and agents, and their respective successors, heirs, and assigns (collectively, the "*TG Indemnities*"), against all liabilities, damages, losses, and expenses (including, without limitation, reasonable attorneys' fees and expenses of litigation) (collectively, "*Losses*") incurred by or imposed upon TG Indemnities, or any of them, as a result of claims, suits, actions, demands, or judgments of Third Parties, including, without limitation, personal injury and product liability claims (collectively, "*Claims*"), arising out of (a) the use of the Licensed Patents, Licensed Technology, LFB Background Patents, and/or Licensed Trademark by or on behalf of Company or any of its Affiliates, Sublicensees, or Distributors; (b) the Development and/or Commercialization of the Product by or on behalf of Company or any of its Affiliates, Sublicensees, or Distributors; (c) any breach of this Agreement by Company or any of its Affiliates, Sublicensees, Distributors, or agents; (d) without limiting the generality of Section 13.1(c), any breach of Section 5.3 of this Agreement, including, without limitation, indemnifying TG Indemnities for all Losses incurred by TG in connection with payment of penalties to LFB under Section 5.4 of the LFB License; and (e) the gross negligence or willful misconduct of any Company Indemnity or Sublicensee of Company; excluding, in each of (a) – (e) above, any Claim or Loss with respect to which TG has an obligation to indemnify Company Indemnities pursuant to Section 13.2, as to which Claim or Loss each Party will indemnify the other to the extent of their respective liability for such Loss (unless such Claim or Loss is otherwise expressly excluded from a Party's indemnification obligations under this Agreement).**

13.2 **Indemnification of Company by TG. TG shall indemnify, defend, and hold harmless Company, its Affiliates, their respective directors, officers, employees, and agents, and their respective successors, heirs, and assigns (collectively, the "*Company Indemnities*"), against**

all Losses incurred by or imposed upon the Company Indemnities, or any of them, as a result of Claims arising out of (a) the Global Development Activities or Commercialization by or on behalf of TG of the Product (i) outside of the Field in the Territory, or (ii) in the Excluded Territory; (b) any breach of this Agreement by TG or any of its Affiliates, (sub)licensees, distributors, or agents; or (c) the gross negligence or willful misconduct of any TG Indemnity or (sub)licensee of TG; excluding, in each of (a) – (c) above, any Claim or Loss with respect to which Company or any of its Affiliates has an obligation to indemnify TG pursuant to Section 13.1, as to which Claim or Loss each Party will indemnify the other to the extent of their respective liability for such Loss.

13.3 **Conditions to Indemnification. A Person seeking indemnification under this Article 13 (the "*Indemnified Party*") in respect of a Claim shall give prompt notice of such Claim to the Party from which indemnification is sought (the "*Indemnifying Party*"). The Indemnified Party shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such Claim; provided, that, the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim.**

13.4 **Insurance. Not later than fifteen (15) days before the date on which Company or any Affiliate or Sublicensee of Company shall, on a commercial basis, make, use, or sell the Product in the Field in the Territory, and at all times thereafter until the expiration of all applicable statutes of limitation pertaining to any such manufacture, marketing, possession, use, sale, or other disposition of the Product, Company will, at its own expense, with respect to the Product in the Field in the Territory, obtain and maintain in full force and effect, comprehensive general liability insurance, in such amounts as is customary in the industry with respect to the development, manufacture, and sale of pharmaceutical products in the Territory. For the avoidance of doubt, all insurance obligations and associated costs for any Company Development Activities and/or Commercialization of the Product in the Field in**

the Territory and over which TG has little or no control, shall be borne solely by Company.

13.5 **Limitation of Liability. EXCEPT AS SET FORTH UNDER SECTIONS 13.1 OR 13.2 OR IN CONNECTION WITH GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR BREACH OF THE PROVISIONS OF ARTICLE 9, OR OTHERWISE AS SET FORTH IN SECTION 5.6: NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (A) ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS, OR LOST REVENUES, OR (B) COST OF PROCUREMENT OF SUBSTITUTE GOODS, KNOW-HOW, OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR OTHER LEGAL OR EQUITABLE THEORY. ADDITIONALLY, NOTHING IN THIS AGREEMENT SHALL REMOVE OR LIMIT EITHER PARTY'S LIABILITY FOR DEATH, PERSONAL INJURY, FRAUD, OR ANY OTHER MATTER OR LIABILITY FOR WHICH, BY LAW, MAY NOT BE REMOVED OR LIMITED.**

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14. MISCELLANEOUS

14.1 **Disputes; Consent to Jurisdiction. The Parties shall use reasonable efforts to settle any disputed matter arising from or related to this Agreement or the breach thereof (each, a "*Dispute*") by promptly referring any such Dispute to the Chief Executive Officer of each Party. If the Chief Executive Officers are unable to resolve any Dispute within [***] ([***]) [***] of the date on which the Dispute was referred to them for resolution, the Dispute shall be subject to the sole jurisdiction of, and venue in, the U.S. federal court of competent jurisdiction located within Wilmington, Delaware, USA (if available), and otherwise the state courts of competent jurisdiction located within Wilmington, Delaware, USA. Company and TG each irrevocably consent to the jurisdiction of such courts, irrevocably waive any objection based on lack of personal jurisdiction or inconvenience of forum, and agree that process may be served in the manner provided herein for giving notices or otherwise as allowed by Delaware or applicable federal law. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional**

relief that is necessary or desirable to protect the rights or property of such Party.

14.2 **Notices. All notices and communications shall be in writing and delivered personally or by internationally-recognized overnight express courier providing evidence of delivery or mailed via certified mail, return receipt requested, addressed as follows, or to such other address as may be designated from time to time:**

If to TG: **TG Therapeutics, Inc.**
3020 Carrington Mill Blvd., Suite 475
Morrisville, NC 27560
Attention: Michael S. Weiss, Executive Chairman and Chief Executive Officer

With a copy to:

DLA Piper LLP (US)
650 South Exeter Street
Suite 1100
Baltimore, MD 21202
Attention: [***]
Tel.: [***]
Fax: [***]

If to Company:

Neuraxpharm Pharmaceuticals S.L.
Avinguda de Barcelona, 69
08970 Sant Joan Despí
Barcelona, Spain
Attn: [***]

Tel: **[***]**

With a copy to:

Clifford Chance PartmbB
Junghofstraße 14
60311 Frankfurt am Main
Attention: **[***]**
Tel.: **[***]**
Fax: **[***]**

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and effective upon actual receipt or, if earlier, (a) three (3) Business Days after deposit with an internationally-recognized overnight express courier with charges prepaid, or

(b) five (5) Business Days after mailed by certified, registered, or regular mail, postage prepaid, in each case addressed to a Parties at its address stated above or to such other address as such Party may designate by written notice given in accordance with this Section 14.2.

14.3 **Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the application of principles of conflicts of law.**

14.4 **Competition Law. TG and Company agree that nothing in this Agreement shall be interpreted in a way that conflicts with EC Regulation 1217/2010 on research and development agreements, or EC Regulation 316/2014 on technology transfer agreements, as issued by the European Commission, or Competition Act 1998 (Research and Development Agreements Block Exemption) Order 2022, in each case, as may be amended or replaced from time to time.**

14.5 **Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors, and permitted assigns.**

14.6 **Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.**

14.7 **Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original and both of which, together, shall constitute a single agreement.**

14.8 **Amendment; Waiver. This Agreement may be amended, modified, superseded, or canceled, and any of the terms of this Agreement may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of either Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.**

14.9 **No Third Party Beneficiaries. Except as set forth in Sections 13.1 and 13.2, no Third Party (including, without limitation, employees of either Party) shall have or acquire any rights by reason of this Agreement.**

14.10 **Purposes and Scope. The Parties hereto understand and agree that this relationship is limited to the activities, rights, and obligations as set forth in this Agreement and the Supply Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede, or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.**

14.11 **Assignment and Successors. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, (a) in whole or in part, to any of its Affiliates, provided, however, that the assigning Party shall continue to remain responsible for the exercise of the rights and the performance of the obligations under this Agreement of any such Affiliates and provided further that, if such assignee ceases to be an Affiliate, such assignment shall be automatically reversed and such assigned rights, obligations and interests shall be deemed automatically by that fact re-assigned to the assigning Party immediately before such cessation, and (b) in whole, but not in part, to any purchaser of all of its assets or all of its assets to which this Agreement relates; provided, however, that any such purchaser shall, for the avoidance of doubt, acknowledge and agree in writing to be bound by the provisions of this Agreement, including, without limitation and for the avoidance of doubt, the**

provisions set forth in Sections 2.2 and 2.4. Notwithstanding any provision to the contrary, Company acknowledges and agrees that TG shall have the right to assign, make collateral assignments of, and/or otherwise encumber, in whole or in part, this Agreement in connection with Third Party financing transactions of TG and/or its Affiliates either on a generally secured basis or, if pertaining exclusively or primarily to this Agreement then only if such collateral assignment or other encumbrance does not and may not, in the ordinary course (which shall, for the avoidance of doubt, include enforcement of such assignment or other encumbrance) , lead to (i) TG no longer being a party to this Agreement and/or (ii) the performance of obligations by TG hereunder being impaired. Additionally, notwithstanding any provision to the contrary, Company shall, and shall request the applicable Permira branded funds managed or advised by Permira Beteiligungsberatungs GmbH (or one of its Affiliates) to in good faith consider inviting TG to participate in a structured auction process regarding the sale of Company or Neuraxpharm group. Should strategic bidders also be invited to participate in such process, Company shall notify TG that a structured sales process has been initiated at the point in time at which an information memorandum or similar marketing material typically used to obtain non-binding offers are sent out to interested parties.

14.12 Force Majeure. Except with respect to breaches of any payment obligations set forth herein: neither Company nor TG shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure. In event of such Force Majeure, the Party affected

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shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

14.13 Interpretation. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to each Party and not in a favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement. In addition, unless a context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, the word "or" is used in the inclusive sense (and/or), and the word "including" is used without limitation and means "including without limitation".

14.14 Integration; Severability. This Agreement, together with the Supply Agreement, sets forth the entire agreement with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to such subject matter. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Agreement shall not be affected.

14.15 Further Assurances. Each of TG and Company agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments, agreements, documents, and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement. Without limiting the generality of the foregoing, Company agrees, from time to time and upon TG's reasonable request, to enter into such further agreements as necessary under Applicable Laws, including, without limitation, data protection agreements, quality agreements, and others, as needed.

14.16 **Joint and several liability. TG Therapeutics, Inc. and TG Biologics, Inc. shall be jointly and severally liable for the obligations of TG under this Agreement.**

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

NEURAXPHARM PHARMACEUTICALS S.L.

By: _____
Name: Burghard Burczyk-Adelsberger
Title: in his capacity as the legal representative of Neuraxpharm HoldCo Iberia S.L.U., being the sole director of Neuraxpharm Pharmaceuticals S.L.

CEO of NEURAXPHARM GROUP

By: _____
Name: Dr. Jörg Thomas Dierks
Title: Chief Executive Officer

TG THERAPEUTICS, INC.

By: _____
Name: Michael S. Weiss
Title: Chief Executive Officer

TG BIOLOGICS, INC.

By: _____
Name: Michael S. Weiss
Title: Chief Executive Officer

SCHEDULE 3.1.2

[***]

1

SCHEDULE 3.2.1(b)

1

SCHEDULE 4.2.2(c)

[***]

1

SCHEDULE 7.3(A)

[***]

1

SCHEDULE 7.3(B)

[***]

1

SCHEDULE 8.3.5

[***]

1

SCHEDULE 8.3.6

[***]

1

SCHEDULE 11.2.5(a)(v)

[***]

1

SCHEDULE 12.2.2(a)

[***]

1

SCHEDULE 12.2.2(b)

[***]

1

SCHEDULE 12.2.2(c)

[***]

1

EXHIBIT A

[***]

1

EXHIBIT B

[***]

EXHIBIT C

PRESS RELEASE

[*To be attached.*]

EXHIBIT D

[***]

Exhibit E

[***]

Exhibit F

[***]

SCHEDULE 5.1

[***]

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: August 4, 2023November 6, 2023

/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: August 4, 2023November 6, 2023

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
TG THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2023September 30, 2023 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: August 4, 2023November 6, 2023

/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 June 30, 2023September 30, 2023 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: August 4, 2023November 6, 2023

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

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