

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

FORM 10-Q

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from to
Commission File Number 001-32639

TG THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

36-3898269
(I.R.S. Employer Identification No.)

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

(877) 575-8489
(Registrants telephone number, including area code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

There were 154,823,137 shares of the registrant's common stock, \$0.001 par value, outstanding as of August 5, 2024.

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

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risks, the risk factors in Item 1A, and any other risks described in the other reports and documents that we have filed with the Securities and Exchange Commission (SEC).

Risks Related to Commercialization

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

Risks Related to Drug Development and Regulatory Approval

- If we are unable to 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 profile following marketing approval, if any, or result in withdrawal from the market if approved.
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials. Moreover, interim, “top-line” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed.
- Any products or product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays, or prevent the receipt of the required approvals.

Risks Related to Governmental Regulation of the Pharmaceutical Industry

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

Risks Related to our Dependence on Third Parties

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

Risks Related to Intellectual Property

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

Risks Related to our Financial Position and Need for Additional Capital

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

General Risk Factors

- Public health issues including an epidemic or global pandemic, including 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 risk of acquiring COVID-19 or lead to more severe complications upon infection. These concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development.
- We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion.
- Our ability to continue our clinical development and commercialization activities will depend on our ability to attract and maintain key management and other personnel.
- Certain of our executive officers, directors and other stockholders own more than 5% of our outstanding common stock and may be able to influence our management and the outcome of matters submitted to shareholders for approval.
- Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition more difficult, which could limit the price investors might be willing to pay for our common stock.
- Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit and could subject us to securities and shareholder derivative litigation.
- Significant disruptions of information technology systems, breaches of data security or unauthorized disclosures of sensitive data could harm our business and subject us to liability or reputational damage.

The foregoing is only a summary of some of our risks. These and other risks are discussed more fully in the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this Quarterly Report on Form 10-Q (our Risk Factors).

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2024 <u>(Unaudited)</u>	December 31, 2023 <u>(Note 1)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,910	\$ 92,933
Short-term investment securities	134,342	124,575
Accounts receivable, net	83,608	51,093
Inventories	81,243	39,823
Prepaid research and development and other current assets	7,047	9,519
Total current assets	389,150	317,943
Restricted cash	1,292	1,285
Long-term investment securities	947	—
Right of use assets	7,663	8,050
Other noncurrent assets(1)	2,155	2,309
Total assets	<u>\$ 401,207</u>	<u>\$ 329,587</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 93,472	\$ 38,471
Other current liabilities	4,162	1,479
Lease liability – current portion	1,306	1,446
Deferred revenue - current portion	3,373	152
Accrued compensation	6,351	12,172
Total current liabilities	108,664	53,720
Deferred revenue, non-current portion	3,743	6,016
Loan payable – non-current	102,537	100,118
Lease liability – non-current	8,695	9,231
Total liabilities	<u>223,639</u>	<u>169,085</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value per share (190,000,000 shares authorized, 154,873,847 and 151,465,598 shares issued, 154,832,538 and 151,424,289 shares outstanding at June 30, 2024 and December 31, 2023, respectively)	155	151
Additional paid-in capital	1,734,052	1,713,162
Treasury stock, at cost, 41,309 shares at June 30, 2024 and December 31, 2023	(234)	(234)
Accumulated deficit	(1,556,405)	(1,552,577)
Total stockholders' equity	<u>177,568</u>	<u>160,502</u>
Total liabilities and stockholders' equity	<u>\$ 401,207</u>	<u>\$ 329,587</u>

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

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

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	\$ 72,596	\$ 16,036	\$ 123,084	\$ 23,801
License, milestone, royalty and other revenue	870	38	13,855	76
Total revenue	<u>\$ 73,466</u>	<u>\$ 16,074</u>	<u>\$ 136,939</u>	<u>\$ 23,877</u>
Costs and expenses:				
Cost of revenue	8,304	1,911	13,745	2,768
Research and development:				
Noncash compensation	2,520	5,664	4,972	7,247
Other research and development	15,036	22,458	45,306	36,744
Total research and development	<u>17,556</u>	<u>28,122</u>	<u>50,278</u>	<u>43,991</u>
Selling, general and administrative:				
Noncash compensation	6,962	6,877	13,848	12,117
Other selling, general and administrative	31,828	23,838	59,522	46,666
Total selling, general and administrative	<u>38,790</u>	<u>30,715</u>	<u>73,370</u>	<u>58,783</u>
Total costs and expenses	<u>64,650</u>	<u>60,748</u>	<u>137,393</u>	<u>105,542</u>
Operating income (loss)	<u>8,816</u>	<u>(44,674)</u>	<u>(454)</u>	<u>(81,665)</u>
Other expense (income):				
Interest expense	3,977	3,627	6,265	6,471
Other income	(1,712)	(691)	(2,592)	(1,295)
Total other expense, net	<u>2,265</u>	<u>2,936</u>	<u>3,673</u>	<u>5,176</u>
Net income (loss) before taxes	<u>\$ 6,551</u>	<u>\$ (47,610)</u>	<u>\$ (4,127)</u>	<u>\$ (86,841)</u>
Income tax benefit	328	—	299	—
Net income (loss)	<u>\$ 6,879</u>	<u>\$ (47,610)</u>	<u>\$ (3,828)</u>	<u>\$ (86,841)</u>
Net income (loss) per common share:				
Basic	\$ 0.05	\$ (0.34)	\$ (0.03)	\$ (0.62)
Diluted	\$ 0.04	\$ (0.34)	\$ (0.03)	\$ (0.62)
Weighted-average shares of common stock outstanding				
Basic	144,727,482	141,503,738	145,464,255	140,911,295
Diluted	159,423,571	141,503,738	145,464,255	140,911,295

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

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

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

	Common Stock		Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at January 1, 2024	151,465,598	\$ 151	\$ 1,713,162	41,309	\$ (234)	\$ (1,552,577)	\$ 160,502
Issuance of common stock in connection with exercise of options	2,500	*	10	—	—	—	10
Issuance of restricted stock	3,304,468	4	(4)	—	—	—	—
Forfeiture of restricted stock	(165,514)	*	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	10,304	—	—	—	10,304
Net loss	—	—	—	—	—	(10,707)	(10,707)
Balance at March 31, 2024	154,607,052	155	1,723,472	41,309	(234)	(1,563,284)	160,109
Issuance of common stock in connection with exercise of options	27,250	*	135	—	—	—	135
Issuance of restricted stock	332,138	*	—	—	—	—	—
Forfeiture of restricted stock	(92,593)	*	—	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	10,445	—	—	—	10,445
Net income	—	—	—	—	—	6,879	6,879
Balance at June 30, 2024	154,873,847	155	1,734,052	41,309	(234)	(1,556,405)	177,568

*Amount less than one thousand dollars

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

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

	Six months ended June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (3,828)	\$ (86,841)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	18,820	19,364
Depreciation and amortization	48	100
Amortization of premium (discount) on investment securities	(3,470)	(487)
Amortization of debt issuance costs	1,278	1,100
Amortization of leasehold interest	106	106
Noncash change in lease liability and right of use asset	905	990
Change in fair value of equity investments	178	—
Change in fair value of notes payable	24	261
Changes in assets and liabilities:		
Increase in inventory	(39,491)	(28,896)
Decrease (increase) in other current assets	2,540	(9,316)
Increase in accounts receivable	(32,515)	(17,484)
Increase in accounts payable and accrued expenses	49,181	19,136
Decrease in lease liabilities	(1,193)	(1,187)
Increase in other current liabilities	3,646	1,323
Increase (decrease) in deferred revenue	1,100	(76)
Net cash used in operating activities	<u>(2,671)</u>	<u>(101,907)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturity of short-term securities	144,900	46,501
Investment in held-to-maturity securities	(151,265)	(22,168)
Investment in long-term securities	(1,125)	—
Net cash (used in) provided by investing activities	<u>(7,490)</u>	<u>24,333</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock, net	—	46,296
Proceeds from exercise of options	145	1,114
Proceeds from debt financings	—	25,000
Financing costs paid	—	(125)
Net cash provided by financing activities	<u>145</u>	<u>72,285</u>
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(10,016)	(5,289)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	94,218	103,577
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	<u>\$ 84,202</u>	<u>\$ 98,288</u>
Reconciliation to amounts on condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 82,910	\$ 97,009
Restricted cash	1,292	1,279
Total cash, cash equivalents and restricted cash	<u>\$ 84,202</u>	<u>\$ 98,288</u>
Cash paid for:		
Interest	\$ 4,936	\$ 3,929

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

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

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

NOTE 1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

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-xiyy) for the treatment of adult patients with RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. TG also received approval for BRIUMVI by the European Commission (EC) in the European Union (EU), and the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK), for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features. TG continues to actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

Basis of Presentation

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

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

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, from our loan and security agreements executed with Hercules Capital, Inc. (Hercules) (see Note 7 for more information), and the upfront payment from the Commercialization Agreement (see Note 2 for more information). 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. During the six months ended June 30, 2024, we generated \$123.1 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 maintain or obtain regulatory approval for our drug candidates. We may continue to incur operating losses even now that we are generating revenues from BRIUMVI.

As of June 30, 2024, we had \$217.3 million in cash and cash equivalents, and investment securities. The Company believes its existing cash, cash equivalents, and investment securities, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will be sufficient to fund its anticipated operating cash requirements for at least twelve months following the date of this filing.

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

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

Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included in our 2023 Annual Report on Form 10-K, except as updated herein or as it relates to revenue recognition, accounts receivable, inventory, cost of revenue, equity securities, and the adoption of new accounting standards during the six months ended June 30, 2024. Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company’s consolidated financial statements.

Financial Statement Reclassification

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

Revenue Recognition

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

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

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

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

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

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

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

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

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

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

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

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

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

License Agreements

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

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

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

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

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

Other Revenue

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

Deferred Product Revenue

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

Accounts Receivable

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

Cost of Revenue

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

Inventory

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

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

Equity Securities

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

Net Income (Loss) Per Common Share

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

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

	As of June 30,	
	2024	2023
Unvested restricted stock	9,872,652	8,324,240
Options	4,667,279	4,799,523
Warrants	312,272	312,272
Shares issuable upon note conversion	21,434	20,323
Total	14,873,637	13,456,358

The computation of basic and diluted EPS is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
(in thousands, except share and per share data)				
Net income (loss)	6,879	(47,610)	(3,828)	(86,841)
Weighted-average common shares outstanding	144,727,482	141,503,738	145,464,255	140,911,295
Dilutive effect of potential common shares	14,696,089	-	-	-
Weighted-average common shares outstanding assuming dilution	159,423,571	141,503,738	145,464,255	140,911,295
Net income (loss) per share - basic	0.05	(0.34)	(0.03)	(0.62)
Net income (loss) per share - diluted	0.04	(0.34)	(0.03)	(0.62)

NOTE 2 REVENUE

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

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Total product revenue, net	\$ 72,596	\$ 16,036	\$ 123,084	\$ 23,801
License Revenue	38	38	76	76
Milestone Revenue	—	—	12,500	—
Royalty Revenue	150	—	183	—
Other Revenue	682	—	1,096	—
Total Revenue	\$ 73,466	\$ 16,074	\$ 136,939	\$ 23,877

Product revenue, net

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

As of June 30, 2024, approximately \$21.6 million of 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 of which the Company previously partnered (the Territory). In addition, the Company will perform certain development and regulatory activities for Neuraxpharm to support its obligations under the Commercialization Agreement to secure and maintain the regulatory approvals required to sell BRIUMVI in the Territory. As part of the overall arrangement, the Company has agreed to supply BRIUMVI to Neuraxpharm throughout the term of the Commercialization Agreement.

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

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

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

The Development and Regulatory Activities performance obligation is satisfied over time because Neuraxpharm simultaneously receives and consumes the benefits provided by the Company's performance of the services. Therefore, revenue is recognized as the activities are completed by the Company. For the three and six months ended June 30, 2024, the Company recognized Other Revenue of \$0.7 million and \$1.1 million, respectively, related to the Development and Regulatory Activities.

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

The performance obligation related to the Supply of Licensed Product is met when control of the product passes to Neuraxpharm. The consideration received from Neuraxpharm for the supply of BRIUMVI will be recognized by the Company as a component of product revenue, net. As of June 30, 2024, the Company has an unconditional right to receive \$0.4 million in consideration from Neuraxpharm related to the performance obligation to supply BRIUMVI, that is recorded as accounts receivable, net. The related performance obligation to supply BRIUMVI has not yet been satisfied, and therefore, as of June 30, 2024, \$7.0 million has been recorded as deferred revenue. The Company will reevaluate the consideration received, and performance obligations satisfied, at the end of each reporting period. Such reevaluations may result in a change to the amount of product revenue, net, recognized and deferred revenue.

The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are highly dependent on factors outside of the Company's control. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue in the period when the related sales threshold is met. All other milestones will be recognized as revenue immediately in the period the achievement of the underlying milestone is probable. In March 2024, the Company received a \$12.5 million milestone payment for the first key market commercial launch of BRIUMVI in the EU. Any consideration related to sales-based royalties will be recognized when the related sales occur. During the three and six months ended June 30, 2024, royalty revenue of \$0.1 million and \$0.2 million, respectively, was recognized.

NOTE 3 INVESTMENT SECURITIES

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

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

(in thousands)	June 30, 2024			
	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 2024 and December 2024) (held-to-maturity)	\$ 134,342	\$ 2	\$ 15	\$ 134,329
Total short-term investments	\$ 134,342	\$ 2	\$ 15	\$ 134,329
	December 31, 2023			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2024 and June 2024) (held-to-maturity)	\$ 124,575	\$ 30	\$ 53	\$ 124,552
Total short-term investments	\$ 124,575	\$ 30	\$ 53	\$ 124,552

Our long-term investments as of June 30, 2024 include shares of common stock of Precision. The fair market value of these equity securities as of June 30, 2024 was \$0.9 million. For the three and six months ended June 30, 2024, we recorded unrealized losses of \$0.4 million and \$0.2 million, respectively, based on the change in fair value of Precision's common stock during the period. See Note 5 for further details.

NOTE 4 INVENTORY

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

	June 30, 2024
Raw Materials	\$ 1,735
Work in Process	77,893
Finished Goods	1,615
Total Inventory	<u>\$ 81,243</u>

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

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

The work in process materials consist primarily of bulk drug substance, which has a multi-year shelf life. When the bulk drug substance is manufactured into BRIUMVI finished goods, those finished goods have a shelf life of three years from the date of manufacture. Our expectation is to sell finished goods at least twelve months prior to expiration. Due to our long manufacturing lead time, it was necessary to buildup inventory in support of BRIUMVI forecasted sales, to ensure appropriate safety stock levels, and meet our commitment to supply BRIUMVI to Neuraxpharm related to the Commercialization Agreement. As a result of being in the early stages of the BRIUMVI product launch, the Company is continuing to evaluate the length of its operating cycle.

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

NOTE 5 FAIR VALUE MEASUREMENTS

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

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

Equity Investments and Forward Contract Liabilities

On January 7, 2024, (the Precision Effective Date) the Company and its wholly-owned subsidiary, TG Cell Therapy, Inc., (TG Cell) entered into a License Agreement (the Precision License Agreement) with Precision, pursuant to which Precision granted the Company certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize Precision's allogeneic CAR T therapy azercabtagene zaprelucecel (azer-cel) for the treatment of autoimmune and other non-oncology diseases and conditions.

Pursuant to the Precision License Agreement, the Company made an upfront payment to Precision of \$7.5 million, consisting of (i) \$5.25 million in cash and (ii) \$2.25 million (the Upfront Precision Stock Payment), as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock at a price of \$0.77 per share. The Company paid a premium for the shares which was recorded in research and development expense as part of the cost of the Precision License Agreement. Precision subsequently had a 30-to-1 reverse stock split in February 2024. The shares purchased with the Upfront Precision Stock Payment are classified as an equity investment and are recognized at fair market value as of June 30, 2024.

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

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

5% Notes

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

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

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

(in thousands)	Financial assets and liabilities at fair value as of June 30, 2024			
	Level 1	Level 2	Level 3	Total
Equity Investments	\$ 947	\$ —	\$ —	\$ 947
Total Assets	\$ 947	\$ —	\$ —	\$ 947
Forward Contract Liabilities	\$ —	\$ 2,703	\$ —	\$ 2,703
5% Notes	\$ —	\$ —	\$ 381	\$ 381
Total Liabilities	\$ —	\$ 2,703	\$ 381	\$ 3,084

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

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

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

NOTE 6 STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

On September 2, 2022, we filed an automatic "shelf registration" statement on Form S-3 (the 2022 WKSJ 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 WKSJ Shelf was declared effective in September 2022. In connection with the 2022 WKSJ Shelf, we entered into an At-the-Market Issuance Sales Agreement (the 2022 ATM) with Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (each a 2022 Agent and collectively, the 2022 Agents), relating to the sale of shares of our common stock. Under the 2022 ATM, we will pay the 2022 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the six months ended June 30, 2023, we sold a total of 1,385,700 shares of common stock under the 2022 ATM for aggregate total gross proceeds of approximately \$47.1 million at an average selling price of \$34.01 per share, resulting in net proceeds of approximately \$46.3 million after deducting commissions and other transactions costs. The 2022 WKSJ Shelf is currently our only active shelf registration statement. We may offer any combination of the securities registered under the 2022 WKSJ 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. We had no activity on the 2022 ATM during the six months ended June 30, 2024.

The 2022 WKSJ Shelf is currently our only active shelf registration statement. We may offer any combination of the securities registered under the 2022 WKSJ 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 17,000,000 shares available to be issued. As of June 30, 2024, 7,353,076 shares of restricted stock and 2,267,500 options were outstanding and up to an additional 5,324,742 shares were available to be issued under the 2022 Incentive Plan.

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (the 2012 Incentive Plan) was approved by stockholders in June 2020. As of June 30, 2024, 4,019,607 shares of restricted stock and 2,399,779 options were outstanding, and no additional shares were available to be issued under the 2012 Incentive Plan as the 2022 Incentive Plan is currently the Company's only active incentive plan.

Stock-based compensation expense included in the condensed consolidated statements of operations was \$9.5 million and \$12.5 million for the three months ended June 30, 2024 and 2023, respectively, and \$18.8 million and \$19.4 million for the six months ended June 30, 2024 and 2023, respectively. The \$9.5 million and the \$18.8 million for the three and six months ended June 30, 2024, respectively, is net of \$1.0 million and \$1.9 million of stock-based compensation expense that was capitalized into inventory, respectively.

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

Stock Options and Restricted Stock

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

	<u>Stock Options</u>	<u>Restricted Stock</u>
Equity awards outstanding, beginning of year	4,697,029	9,639,068
Changes during the year:		
Granted	—	3,636,606
Exercised or vested	(29,750)	(1,644,884)
Expired or Forfeited	—	(258,107)
Equity awards outstanding, end of period	<u>4,667,279</u>	<u>11,372,683</u>

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

(in thousands)	<u>Stock Options</u>	<u>Restricted Stock</u>
Unrecognized compensation cost	\$2,517	\$50,026
Expected weighted-average period in years of compensation cost to be recognized	2.1	3.0

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 (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.

NOTE 7 LOAN PAYABLE

On February 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, 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 (the Amended Loan Agreement Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (as amended, restated and/or modified from time to time, 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 to January 1, 2026, (v) reset and extend the interest only period from April 1, 2021 to February 1, 2025 and extendable to 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.

On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended Loan 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 (the Tranche 3B Advance and the 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 to 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 contains financial covenants that require the Company to maintain certain levels of unrestricted cash and additional financial covenants related to market capitalization. As of June 30, 2024, we are in compliance with all financial covenants under the Amended Loan Agreement.

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, 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 three months ended March 31, 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

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 \$1.3 million and \$1.1 million for the six months ended June 30, 2024, and 2023, respectively. At June 30, 2024, the remaining unamortized balance of debt issuance costs was \$3.8 million.

The loan payable as of June 30, 2024 and December 31, 2023, is as follows:

(in thousands)	June 30, 2024	December 31, 2023
Loan payable	\$ 95,000	\$ 95,000
Add: Accreted Liability of final payment fee	11,371	10,230
	106,371	105,230
Less: unamortized debt issuance costs	(3,834)	(5,112)
	102,537	100,118
Less: principal payments	—	—
Total loan payable	102,537	100,118
Less: current portion	—	—
Loan payable non-current	\$ 102,537	\$ 100,118

Refer to Note 11 for a discussion of the full repayment of this loan payable in August 2024.

NOTE 8 LEASES

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

In October 2019, we finalized a five-year lease for office space in New Jersey (the NJ Lease). We approximate an average annual rental obligation of \$0.3 million under the NJ Lease. We took possession of this space in October 2019, with rental payments beginning in November 2019. We incurred rental expense of \$0.1 million for the six months ended June 30, 2024.

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

At January 1, 2019, we recognized a lease liability and corresponding Right-of-Use (ROU) asset of \$9.5 million and \$8.1 million, respectively, based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. The present values of our lease liability and corresponding ROU asset are \$10.0 million and \$7.7 million, respectively, as of June 30, 2024. Our leases have remaining lease terms of 6 months to 7 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 six months ended June 30, 2024 and 2023:

(in thousands)	Three months ended		Six months ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Operating lease cost	\$ 551	\$ 552	\$ 1,151	\$ 1,096
Net lease cost	\$ 551	\$ 552	\$ 1,151	\$ 1,096

As of June 30, 2024, the weighted-average remaining operating lease term was 5.6 years and the weighted-average discount rate for operating leases was 10.01%. Cash paid for amounts included in the measurement of operating lease liabilities during the six months ended June 30, 2024 was \$1.2 million. The balance sheet classification of lease liabilities was as follows:

(in thousands)	June 30, 2024	December 31, 2023
Liabilities		
Lease liability current portion	\$ 1,306	\$ 1,446
Lease liability non-current	8,695	9,231
Total lease liability	<u>\$ 10,001</u>	<u>\$ 10,677</u>

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

(in thousands)	Operating leases
Remainder of 2024	\$ 1,195
2025	2,100
2026	2,080
2027	1,913
2028	1,827
After 2029	4,715
Total lease payments	13,830
Less: interest	(3,829)
Present value of lease liabilities(*)	<u>\$ 10,001</u>

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

NOTE 9 LICENSE AGREEMENTS

BRIUMVI (Ublituximab)

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the LFB License Agreement). Under the terms of the LFB License Agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. As of June 30, 2024, we have incurred approximately \$31.0 million in expense related to the achievement of certain milestones of the LFB License Agreement.

LFB Group is eligible to receive royalty payments on net sales of ublituximab at a royalty rate that escalates from mid-single digits to high-single digits. The license will terminate on a country-by-country basis upon the expiration of the last licensed patent right or 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 six months ended June 30, 2024, the Company recorded \$7.2 million and \$12.1 million, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of revenue based on sales of BRIUMVI in the U.S. and the EU, compared to \$1.5 million and \$2.3 million during the three and six months ended June 30, 2023, respectively, related to the worldwide royalty due under the LFB License Agreement in cost of revenue based on U.S. sales of BRIUMVI. As of June 30, 2024, \$7.2 million in royalties were payable under the LFB License Agreement.

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

An upfront payment of \$2.0 million, which was received in December 2012, net of \$0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 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, 2024 and 2023. At June 30, 2024 and December 31, 2023, we have deferred revenue of approximately \$0.2 million and \$0.3 million, respectively, associated with this \$2 million payment (approximately \$0.2 million of which has been classified in current liabilities at June 30, 2024 and December 31, 2023).

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

In July 2023, the Company entered into the Commercialization Agreement with Neuraxpharm. The Company granted Neuraxpharm the exclusive right to commercialize BRIUMVI in territories outside the United States, Canada, and Mexico, which are retained by TG, and excluding certain Asian countries previously partnered. Under the terms of the Commercialization Agreement, the Company received a one-time, non-refundable payment of \$140.0 million upon contract execution (please refer to Note 2 – Revenue). In March 2024, the Company received a \$12.5 million milestone payment upon the first key market commercial launch in the EU. The Company is eligible to receive up to an additional \$492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. In addition, TG will receive tiered double-digit royalties on net product sales up to 30%. Royalty revenue of \$0.1 million and \$0.2 million was recognized during the three and six months ended June 30, 2024, respectively. In the event of a change of control of the Company (as defined in the Commercialization Agreement), the Company retains an option to buy back all rights under the Commercialization Agreement for a period of two years thereafter.

Azer-cel

On January 7, 2024, the Company and its wholly-owned subsidiary, TG Cell Therapy, Inc., entered into the Precision License Agreement with Precision, pursuant to which Precision granted the Company certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize Precision's allogeneic CAR T therapy azercabtagene zapreleucel (azer-cel) for the treatment of autoimmune and other non-oncology diseases and conditions.

Pursuant to the Precision License Agreement, the Company made an upfront payment to Precision of \$7.5 million, consisting of (i) \$5.25 million in cash and (ii) \$2.25 million, as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock at a price of \$0.77 per share. Within 12 months of the Precision License Agreement, the Company will make a deferred payment of \$2.5 million to Precision, consisting of an equity investment in Precision's common stock at a 100% premium to the 30-day volume-weighted average price (the 30-day VWAP) prior to purchase. Upon achievement of certain near-term clinical or time-based milestones, the Company will make a \$7.5 million payment to Precision, a portion of which will also be an equity investment in Precision's common stock at a 100% premium to the 30-day VWAP prior to purchase. Precision will be eligible to receive up to \$293 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity, and a period of ten years following the first commercial sale of the licensed product in such country. The Company has also agreed to make certain payments to Precision's licensors during the term of the Precision License Agreement.

NOTE 10 RELATED PARTY TRANSACTIONS

In July 2015, we entered into a Shared Services Agreement (the Shared Services Agreement) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. The Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately \$0.9 million and \$0.5 million for the six months ended June 30, 2024 and 2023, respectively, primarily related to shared personnel. Mr. Weiss, our Chairman and Chief Executive Officer, also serves as a director and Executive Vice Chairman, Strategic Development of FBIO.

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

NOTE 11 SUBSEQUENT EVENTS

Term Loan Facility

On August 2, 2024, the Company entered into a term loan facility of \$250 million (the Initial Term Loan) with Blue Owl Capital Corporation, as administrative agent (the Administrative Agent), HealthCare Royalty and Blue Owl Capital under the Financing Agreement (as defined below). The Initial Term Loan is governed by a financing agreement, dated August 2, 2024 (the Financing Agreement), which provides for (i) a single draw of the Initial Term Loan on the Closing Date and (ii) an uncommitted additional facility in an aggregate principal amount of \$100 million.

The Initial Term Loan will mature on August 2, 2029 (the Term Loan Maturity Date). The Initial Term Loan accrues interest at a per annum rate of interest equal to an applicable margin plus, at the Company's option, either (a) at a base rate determined by reference to the highest of (1) the prime rate published by the Wall Street Journal, (2) the federal funds effective rate plus 0.50% and (3) Term SOFR, plus 1.00% or (b) Term SOFR, which, shall be no less than 1.00%. The applicable margin for borrowings of the Initial Term Loan is determined on a quarterly basis by reference to a pricing grid based on the achievement of US Net Sales (as defined in the Financing Agreement) for the most recently completed four consecutive fiscal quarters of the Company and its Subsidiaries (as defined in the Financing Agreement). The pricing grid commences at 5.50% for SOFR borrowings and 4.50% for base rate borrowings and is subject to a 25 basis point step-down upon achievement of a specified US Net Sales threshold. The Initial Term Loan requires scheduled quarterly amortization payments, commencing with the fiscal quarter ending June 30, 2028, in an amount equal to \$12.5 million, with the balance due and payable on the Term Loan Maturity Date; provided that such amortization payments may be deferred to the Term Loan Maturity Date upon the achievement of a Total Net Leverage Ratio (as defined in the Financing Agreement) that is less than or equal to an agreed threshold.

The Initial Term Loan is secured by a lien on substantially all of the assets of the Company and certain subsidiaries of the Company as guarantors and contains customary covenants and representations.

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

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

Share Repurchase Program

On August 2, 2024, the Company announced that the Board of Directors (the Board) of the Company had authorized and approved a share repurchase program for up to \$100 million of the currently outstanding shares of the Company's common stock. Under the share repurchase program, the Company intends to repurchase shares through open market purchases, privately-negotiated transactions, block purchases or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934, as amended (the Exchange Act).

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

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

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

OVERVIEW

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

Recent Business Update Highlights

Ublituximab Development

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

Pipeline

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

Corporate Update

In August 2024 we announced the establishment of a new five year, \$250 million credit facility with HealthCare Royalty and Blue Owl Capital, primarily to repay \$107 million in outstanding debt and accrued interest, which was set to mature in multiple tranches from mid-2025 to January 2026 and to fund the buyback of up to \$100 million of currently outstanding shares of our common stock. The remainder will be available for working capital purposes, providing us with additional operational flexibility.

BRIUMVI Patents

In February 2024, we announced the issuance of three additional patents by the United States Patent and Trademark Office (USPTO) for BRIUMVI, which extended patent protection through 2042.

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 August 2024.

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

BRIUMVI (ublituximab-xiiy) Overview

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

The BRIUMVI approvals were primarily based on the ULTIMATE I and ULTIMATE II Phase 3 trials. Each trial was an independent global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing the efficacy and safety/tolerability of ublituximab (450mg dose administered by one-hour intravenous infusion every 6 months, following a day 1 infusion of 150mg over four hours and a day 15 infusion of 450mg over one hour) versus teriflunomide (14mg oral tablets taken once daily) in subjects with RMS. These trials were conducted under a special protocol assessment (SPA) with the FDA. The ULTIMATE I and II trials were led by Lawrence Steinman, MD, Zimmermann Professor of Neurology and Neurological Sciences, Pediatrics, and Genetics at Stanford University. Full enrollment was completed in October 2018, with approximately 1,100 subjects enrolled in both studies combined.

- In December 2020, we announced positive topline results from the ULTIMATE I & II trials. Both studies met their primary endpoint of significantly reducing ARR over a 96-week period ($p < 0.005$ in each study) with BRIUMVI demonstrating an ARR of < 0.10 in each of the studies. Relative reductions of approximately 60% and 50% in ARR over teriflunomide were observed in ULTIMATE I & II, respectively. Key secondary MRI endpoints were also met.
- On August 22, 2022, the full results from the ULTIMATE I & II trials were published in the New England Journal of Medicine.
- Additional exploratory data sets from the ULTIMATE I & II Phase 3 trials continue to be presented at major medical meetings. BRIUMVI is also being studied in the ENHANCE Phase 3b trial evaluating RMS patients who switch from a IV anti-CD20 therapy to BRIUMVI and data from the ENHANCE trial was most recently presented at the 2024 Americas Committee for Treatment and Research in Multiple Sclerosis Annual Meeting held in February 2024.
- On February 27, 2024, we announced the issuance of three additional patents by the United States Patent and Trademark Office (USPTO) for BRIUMVI, which extended patent protection through 2042.
- In August 2024, we announced the initiation of a Phase 1 clinical trial evaluating a subcutaneous formulation of ublituximab in patients with RMS and that the first patients have been dosed.

U.S. Commercialization of BRIUMVI

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

Ex-U.S. Commercialization of BRIUMVI

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

On August 1, 2023, we announced an agreement with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), a leading European specialty pharmaceutical company focused on the treatment of CNS disorders, for the Ex-U.S. commercialization of BRIUMVI (Commercialization Agreement). Under the terms of the Commercialization Agreement, we received an upfront payment of \$140 million, and 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 U.S., Canada and Mexico, which are retained by TG, and excluding certain Asian countries of which the Company previously partnered. We retain an option to buy back all rights under the Commercialization Agreement for a period of two years in the event of a change in control of TG.

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

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

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

RESULTS OF OPERATIONS

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

(in thousands)	Three months ended June 30,	
	2024	2023
Product revenue, net	\$ 72,596	\$ 16,036
License, milestone, royalty and other revenue	870	38
Total Revenue	\$ 73,466	\$ 16,074
Costs and expenses:		
Cost of revenue	8,304	1,911
Research and development:		
Noncash compensation	2,520	5,664
Other research and development	15,036	22,458
Total research and development	17,556	28,122
General and administrative:		
Noncash compensation	6,962	6,877
Other selling, general and administrative	31,828	23,838
Total general and administrative	38,790	30,715
Total costs and expenses	64,650	60,748
Interest expense	3,977	3,627
Other income	(1,712)	(691)
Total other expense, net	2,265	2,936
Net income (loss) before taxes	6,551	(47,610)
Income tax benefit	328	—
Net income (loss)	\$ 6,879	\$ (47,610)

Product Revenue, Net. Product revenue, net was approximately \$72.6 million for the three months ended June 30, 2024, compared to \$16.0 million for the three months ended June 30, 2023. Product revenue, net for the both the three months ended June 30, 2024 and June 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. The increase in product revenue, net is driven by an increase in product shipments for BRIUMVI as a result of greater market penetration.

License Revenue. License revenue was less than \$0.1 million for the three months ended June 30, 2024 and June 30, 2023. License revenue for both the three months ended June 30, 2024 and June 30, 2023 is predominantly comprised of recognition of a portion of the upfront payment from the Ublituximab sublicense agreement with Ildong.

Other Revenue. Other revenue was approximately \$0.7 million and zero for the three months ended June 30, 2024 and June 30, 2023, respectively. Other revenue for the three months ended June 30, 2024 is comprised of consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement.

Cost of Revenue. Cost of revenue for the three months ended June 30, 2024 was \$8.3 million compared to approximately \$1.9 million for the three months ended June 30, 2023. Cost of revenue for both the three months ended June 30, 2024 and June 30, 2023 consists primarily of third-party manufacturing, distribution, overhead costs and royalties owed to our licensing partner for BRIUMVI sales. A portion of the costs of producing BRIUMVI sold to date was expensed as research and development prior to the FDA approval of BRIUMVI and therefore it is not reflected in the cost of revenue. As a result, our initial product gross margin is higher as our pre-launch inventory costs are not included in cost of revenue. We expect the cost of revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories. We expect to use the remaining pre-commercialization inventory for product sales through the first quarter of 2025, after which our product gross margin is anticipated to decrease modestly. The cost of revenue for both the three months ended June 30, 2024 and June 30, 2023 includes, respectively, \$0.7 million and zero, costs related to delivering regulatory support & development services to Neuraxpharm in accordance with the Commercialization Agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$2.5 million for the three months ended June 30, 2024, as compared to \$5.7 million during the comparable period ended June 30, 2023. The decrease in noncash compensation expense was primarily due to decreased vesting of milestone-based grants during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023.

Other Research and Development Expense. Other research and development expense decreased for the three months ended June 30, 2024, by approximately \$7.4 million to \$15.0 million as compared to the comparable period ended June 30, 2023. The decrease in research and development expense during the three months ended June 30, 2024 was primarily due to reduced clinical trial related expense and license milestones incurred during the period.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled \$7.0 million for the three months ended June 30, 2024, as compared to \$6.9 million during the comparable period ended June 30, 2023.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled \$31.8 million for the three months ended June 30, 2024, as compared to \$23.8 million during the comparable period ended June 30, 2023. The increase was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the commercialization of BRIUMVI, during the three months ended June 30, 2024.

Interest Expense. Interest expense increased by \$0.4 million to \$4.0 million for the three months ended June 30, 2024, as compared to \$3.6 million for the three months ended June 30, 2023.

Other Income. Other income increased by \$1.0 million to \$1.7 million for the three months ended June 30, 2024 as compared to the three months ended June 30, 2023. The increase is mainly due to higher interest income received from our money market investments.

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

(in thousands)	Six months ended June 30,	
	2024	2023
Product revenue, net	\$ 123,084	\$ 23,801
License, milestone, royalty and other revenue	13,855	76
Total Revenue	\$ 136,939	\$ 23,877
Costs and expenses:		
Cost of revenue	13,745	2,768
Research and development:		
Noncash compensation	4,972	7,247
Other research and development	45,306	36,744
Total research and development	50,278	43,991
General and administrative:		
Noncash compensation	13,848	12,117
Other selling, general and administrative	59,522	46,666
Total general and administrative	73,370	58,783
Total costs and expenses	137,393	105,542
Interest expense	6,265	6,471
Other income	(2,592)	(1,295)
Total other expense, net	3,673	5,176
Net loss before taxes	(4,127)	(86,841)
Income tax benefit	299	—
Net loss	\$ (3,828)	\$ (86,841)

Product Revenue, Net. Product revenue, net was approximately \$123.1 million for the six months ended June 30, 2024, compared to \$23.8 million for the six months ended June 30, 2023. Product revenue, net for the both the six months ended June 30, 2024 and June 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. The increase in product revenue, net is driven by an increase in product shipments for BRIUMVI as a result of greater market penetration.

License Revenue. License revenue was \$12.6 million for the six months ended June 30, 2024 compared to approximately \$0.1 million for the six months ended June 30, 2023. License revenue for the six months ended June 30, 2024 is predominantly comprised of a milestone payment under the Neuraxpharm Commercialization Agreement for the first key market commercial launch of BRIUMVI in the EU. License revenue for the six months ended June 30, 2023 is comprised of recognition of a portion of the upfront payment from the Ublituximab sublicense agreement with Ildong.

Other Revenue. Other revenue was approximately \$1.3 million and zero for the six months ended June 30, 2024 and June 30, 2023, respectively. Other revenue for the six months ended June 30, 2024 is comprised mainly of consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement.

Cost of Revenue. Cost of revenue for the six months ended June 30, 2024 was \$13.7 million compared to approximately \$2.8 million for the six months ended June 30, 2023. Cost of revenue for both the six months ended June 30, 2024 and June 30, 2023 consists primarily of third-party manufacturing, distribution, overhead costs and royalties owed to our licensing partner for BRIUMVI sales. A portion of the costs of producing BRIUMVI sold to date was expensed as research and development prior to the FDA approval of BRIUMVI and therefore it is not reflected in the cost of revenue. As a result, our initial product gross margin is higher as our pre-launch inventory costs are not included in cost of revenue. We expect the cost of revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories. We expect to use the remaining pre-commercialization inventory for product sales through the first quarter of 2025, after which our product gross margin is anticipated to decrease modestly. The cost of revenue for the six months ended June 30, 2024 includes \$1.1 million of costs related to delivering regulatory support & development services to Neuraxpharm in accordance with the Commercialization Agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$5.0 million for the six months ended June 30, 2024, as compared to \$7.2 million during the comparable period ended June 30, 2023. The decrease in noncash compensation expense was primarily due to decreased vesting of milestone-based grants during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023.

Other Research and Development Expense. Other research and development expense increased for the six months ended June 30, 2024, by approximately \$8.6 million to \$45.3 million as compared to the comparable period ended June 30, 2023. The increase in research and development expense during the six months ended June 30, 2024 was primarily attributable to the Precision License Agreement, as well as manufacturing related expenses during the period, offset by a decrease in clinical trial expenses.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled \$13.8 million for the six months ended June 30, 2024, as compared to \$12.1 million during the comparable period ended June 30, 2023. The increase in noncash compensation expense was primarily due to greater vesting of equity grants during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses totaled \$59.5 million for the six months ended June 30, 2024, as compared to \$46.7 million during the comparable period ended June 30, 2023. The increase was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the commercialization of BRIUMVI, during the six months ended June 30, 2024.

Interest Expense. Interest expense decreased by \$0.2 million to \$6.3 million for the six months ended June 30, 2024, as compared to \$6.5 million for the six months ended June 30, 2023.

Other Income. Other income increased by \$1.3 million to \$2.6 million for the six months ended June 30, 2024 as compared to the six months ended June 30, 2023. The increase is mainly due to greater accretion income earned from short-term investment securities during the six months ended June 30, 2024 compared to the comparable period ending June 30, 2023.

LIQUIDITY AND CAPITAL RESOURCES

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

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, our loan and security agreements executed with Hercules (see Note 7 for more information), and the upfront payment from the Commercialization Agreement (see Note 2 for more information). 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. During the six months ended June 30, 2024, we generated \$123.1 million in product revenue from 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 maintain or obtain regulatory approval for our drug candidates. We may continue to incur operating losses even now that we are generating revenues from BRIUMVI.

As of June 30, 2024, we had \$217.3 million in cash and cash equivalents, and investment securities. The Company believes its existing cash, cash equivalents, and investment securities, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will be sufficient to fund its anticipated operating cash requirements for at least twelve months following the date of this filing.

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

Discussion of Cash Flows

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

(in thousands)	Six months ended June 30,	
	2024	2023
Net cash used in operating activities	\$ (2,671)	\$ (101,907)
Net cash used in investing activities	\$ (7,490)	\$ 24,333
Net cash provided by (used in) financing activities	\$ 145	\$ 72,285

Cash used in operating activities for the six months ended June 30, 2024 was \$2.7 million as compared to cash used in operating activities of \$101.9 million for the six months ended June 30, 2023. The decrease in net cash used in operating activities was due to a lower net loss during the six months ended June 30, 2024, offset by an increase in inventory of \$39.5 million during the same period. This inventory balance increase was due to the buildup of inventory in support of BRIUMVI forecasted sales, to ensure appropriate safety stock levels, and meet our commitment to supply BRIUMVI to Neuraxpharm in relation to the Commercialization Agreement.

Net cash used in investing activities for the six months ended June 30, 2024 was \$7.5 million as compared to \$24.3 million provided by investing activities for the six months ended June 30, 2023. The increase in net cash used in investing activities was primarily due to increased investment in short-term securities during the six months ended June 30, 2024.

Net cash provided by financing activities for the six months ended June 30, 2024 was approximately \$0.1 million as compared to net cash provided by financing activities of \$72.2 million for the six months ended June 30, 2023. The decrease in net cash provided by financing activities during the six months ended June 30, 2024 is due to the advance of \$25.0 million drawn as part of the First Amendment entered into with Hercules on March 31, 2024 and \$46.3 million received under 2022 ATM that occurred during the six months June 30, 2023.

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 2023 Annual Report on Form 10-K for the year ended December 31, 2023 and refer to Note 1 in this Quarterly Report on Form 10-Q for significant accounting policies due to commercialization for revenue recognition, gross-to-net sales adjustments, accounts receivable, inventory, and cost of revenue. Of these policies, the following are considered critical to an understanding of our Unaudited Condensed Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments: stock-based compensation expenses, and fair value measurement of financial liabilities. Refer to "Note 2 –Revenue", "Note 5 - Fair Value Measurements" and "Note 6 – Stockholders' Equity" respectively, for more information.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk has not changed materially since our disclosure in Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2024, our disclosure controls and procedures were not effective due to the material weakness in internal control over financial reporting described below.

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

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The Company identified that a process-level control over share-based payment awards was not designed effectively. This ineffectively designed control was attributable to insufficient risk assessment with regards to non-routine share-based payment awards.

This control deficiency resulted in immaterial misstatements in related accounts. Furthermore, the control deficiency described above created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis. Therefore, we concluded that the deficiency represents a material weakness in the Company’s internal control over financial reporting and our internal control over financial reporting was not effective as of June 30, 2024.

Management’s Plan to Remediate the Identified Material Weakness

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

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

Changes in Internal Control Over Financial Reporting

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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS.

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

Risks Related to Commercialization

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

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

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

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

In addition, global health concerns (such as 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 viruses (such as COVID-19) or lead to more severe complications or outcomes upon infection, including death. These or other similar concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development.

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

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

Regulatory approvals for our product or any of our product candidates may be subject to conditions and limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing testing, including Phase 4 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, the approval is subject to certain post-marketing requirements and commitments, including long-term safety studies, as well as studies to evaluate the effects of BRIUMVI in pregnant women and pediatric populations, among others. Similar post-approval studies are required by other regulatory authorities outside of the U.S., including but not limited to, the EMA in the EU and the MHRA in the UK. These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market BRIUMVI, or negatively impact its overall clinical profile.

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

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

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

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

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

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

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

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

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

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and commercialization resources. Large pharmaceutical companies have extensive experience commercializing products and may have significant existing relationships with customers and more resources available to them to promote their products. Many are active in the same diseases that we are, including within the neurological and immunological fields, some in direct competition with us. We may also compete with these organizations to recruit commercial and other key personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

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

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

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

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

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

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products, even if more of our product candidates obtain marketing approval. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. On April 27, 2023, we received a product-specific J-Code for BRIUMVI (J2329), which became 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 may nevertheless still require documented proof that patients meet certain eligibility criteria in order to be reimbursed for BRIUMVI.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any contracts that we enter into with government entities may involve future funding and compliance risks. Such contracts with government entities are generally subject to risks such as lack of funding and compliance with unique requirements. For example, government contract purchase obligations are typically subject to the availability of funding, which may be eliminated or reduced. In addition, the future volume of products or services purchased by a government customer is often uncertain. Any of our government contracts might not be renewed or might be terminated for convenience with little prior notice. Contracts with government entities typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting, and other requirements. These contractual and legal requirements could complicate our business and increase our compliance burden. The occurrence of any of these risks could harm our reputation and might have a materially adverse impact on our business operations and our financial position or results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception, and we may incur losses in the future.

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

Since inception, we have focused our efforts and financial resources on clinical trials, manufacturing of our products and product candidates 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, as well as significant commercialization and outsourced-manufacturing expenses as we continue to commercialize BRIUMVI. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

To become and remain profitable, we must succeed in developing (or in-licensing) and commercializing our products or product 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 products and product candidates; and (ii) manufacturing, marketing and selling our product and product candidates. Our ability to generate sustained revenue depends on a number of factors, including, but not limited to, our ability to:

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

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

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

The development of pharmaceuticals is capital-intensive. We are also continuing to generate additional clinical data for BRIUMVI to support and potentially expand commercial adoption, including assessing long-term tolerability in 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 or with alternate methods of administration. Moreover, now that we have launched BRIUMVI, we will need to expend substantial resources on maintaining approvals and continuing commercialization, manufacturing and distribution over the foreseeable future. Additionally, we expect to commence a trial evaluating azer-cel in autoimmune disease in 2024.

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

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

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

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

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or other arrangements. We do not have any committed external source of funds, other than funds already borrowed under the financing agreement that we entered into with Blue Owl Capital Corporation, HealthCare Royalty and Blue Owl Capital in August 2024 (see Note 7 and Note 11 to our condensed consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or products and product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, which could limit our ability to expand our business operations and could harm our overall business prospects.

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

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

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

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

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

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

On August 2, 2024, the Company entered into a term loan facility of \$250 million (the Initial Term Loan) with Blue Owl Capital Corporation, as administrative agent (the Administrative Agent), HealthCare Royalty and Blue Owl Capital under the Financing Agreement (as defined below).

The Initial Term Loan is governed by a financing agreement, dated August 2, 2024 (the Financing Agreement), which provides for (i) a single draw of the Initial Term Loan on the Closing Date and (ii) an uncommitted additional facility in an aggregate principal amount of \$100 million (*see* Note 11 to our condensed consolidated financial statements for more information).

All obligations under the Financing Agreement are secured by a lien on substantially all of assets of the Company and certain of our subsidiaries as guarantors. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing its outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

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

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

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

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

Failure to satisfy our current and future debt obligations under the Amended Loan Agreement, as amended, 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 Amended Loan Agreement, as amended, 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 Amended Loan Agreement, as amended, 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 did not maintain any bank accounts with Silicon Valley Bank or Signature Bank, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Any failure of a depository institution to return any of our deposits, or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

Risks Related to Drug Development and Regulatory Approval

If we are unable to 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;
- 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,” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.

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

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

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data 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.

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

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

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

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

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- the FDA or other regulatory authorities or institutional review boards (IRBs) or ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or in a country; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors, including our clinical trial sites, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to or regulatory authorities or IRBs or ECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises international conflicts such as the Russian invasion of Ukraine or the Israel-Hamas war, economic instability, or natural disasters;
- regulatory authorities may revise the requirements applicable to our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs or ECs to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies in the same or a similar class that raise safety or efficacy concerns about our product candidates.

We also could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data and Safety Monitoring Board (DSMB) for such trial or by the FDA or other regulatory authorities. Such regulatory authorities may impose a 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. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. If we are not able to adhere to these new requirements, our ability to conduct clinical trials may be delayed or halted. Our drug development costs will also increase if we experience delays in testing or regulatory approvals. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower-than-expected event rates. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly. We may also incur additional costs if enrollment is increased.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To the extent possible and commercially practicable, we plan to develop back-up strategies for raw materials, 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, if applicable, and corresponding state agencies to ensure strict compliance with cGMP requirements and other state and federal regulations. Where manufactured products are globally registered, similar regulatory inspection burdens are applicable from each and every marketed territory. If our manufacturing partners are inspected and deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

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

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

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

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

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

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

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

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

There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, limit price increases, evaluate the relationship between pricing and manufacturer patient programs, and reform government health care program reimbursement methodologies for prescription drugs. For example, the Bipartisan Budget Act of 2018 (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 (DHHS) to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs selected on August 29, 2023, and the first year of maximum price applicability to begin in 2026. On October 3, 2023, the Centers for Medicare & Medicaid Services announced that all manufacturers of the initially selected drugs opted to participate. The Act further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the Act creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending at \$2,000 beginning in 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. For example, life sciences companies have faced enforcement actions under the False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product, among other activities. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute or the Federal Food, Drug, and Cosmetic Act (FDCA) constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, has fraud provisions that impose criminal and civil liability for knowingly and willingly executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs, or integrity oversight and reporting obligations to resolve allegations of non-compliance;
- the Physician Payments Sunshine Act under section 6002 of the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to monitor and report certain information related to payments and other transfers of value to and the ownership and investment interests of physicians and certain other healthcare providers as well as teaching hospitals to the federal government for redisclosure to the public. The Centers for Medicare & Medicaid Services (CMS) has the potential to impose penalties for violations of the Physician Payment Sunshine Act, depending on the circumstances, and reported payments also have the potential to draw scrutiny to our relationships with health care practitioners and academic medical institutions, which may have implications under the Anti-Kickback Statute and other healthcare laws;
- HIPAA, as amended by the HITECH and other amendments, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
- the FDCA and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the Drug Supply Chain Security Act (DSCSA), which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the U.S.; and
- state law equivalents of some of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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

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

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

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

Within the United States, HIPAA establishes a federal “floor” with respect to privacy, security, and breach notification requirements as it pertains to protected health information subject to HIPAA and does not supersede any state laws insofar as they are broader or more stringent than HIPAA. There are numerous other laws, regulations and legislative and regulatory initiatives at the federal and state levels addressing privacy and security of personal data. Depending on the data we receive, we may be subject to federal and state privacy-related laws that may be more restrictive or contain different requirements than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties and requirements related to such data. HIPAA affects the ability of healthcare providers and other entities with which we may interact, including clinical trial sites, to disclose patient health information to us. Under Section 5(a) of the Federal Trade Commission Act (FTCA), the Federal Trade Commission (FTC) expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC has asserted authority and issued enforcement actions in response to actual or perceived unfair or deceptive practices by a company in the handling of consumer information. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act (CCPA), went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. Colorado, Connecticut, Washington, Utah, Virginia and Iowa have also enacted data privacy statutes. Among other things, these state-specific laws create new data privacy obligations for covered companies and provide new privacy rights to state residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The Washington My Health My Data Act also contains a private right of actions. Draft regulations implementing certain of the state statutes have been published, but many questions remain as to how all of the new statutes will be interpreted. In addition to the laws discussed above, we may see more stringent federal and state privacy legislation passed in 2024 and beyond, as the increased cyber-attacks during the ongoing COVID-19 pandemic have once again put a spotlight on data privacy and security in the U.S. and other jurisdictions. We cannot predict where new legislation might arise, the scope of such legislation, or the potential impact to our business and operations. We expect to incur additional costs to ensure that our data privacy and security policies, procedures, and activities comply with applicable and evolving legal requirements.

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

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

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

We expect to operate a portion of our business in certain countries through subsidiaries or through supply, marketing, and distributor arrangements. In those countries where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax laws. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries, and it may adversely affect our business and results of our operations. In all interactions with foreign regulatory authorities and other government agencies, we are exposed to liability risks under the Foreign Corrupt Practices Act (FCPA) or similar anti-bribery laws. We may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, and currency exchange regulations, which we collectively refer to as Trade Control Laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, similar anti-bribery laws, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges, including the Nasdaq Stock Market, for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by U.S., or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

Moreover, our current long-term supply agreement for BRIUMVI contains certain minimum purchases in what are commonly referred to as a “take or pay” provision, and it is possible that future supply agreements could contain such provisions. To the extent our demand does not meet the minimum supply required amounts, we would be forced to pay more than desired. This could create a situation where we are spending more than required and could impact our 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.

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

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

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

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

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

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

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

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

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

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

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

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

On July 28, 2023, we entered into a commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), pursuant to which Neuraxpharm has the right to commercialize BRIUMVI in certain markets outside of the U.S. On February 26, 2024, Neuraxpharm announced the commercial launch of BRIUMVI in Germany and expects to launch BRIUMVI in additional international markets as well. In addition to the Commercialization Agreement, we may enter into collaboration arrangements with other collaboration and commercialization partners.

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

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

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

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

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

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

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the proposed collaborator's resources and expertise, the terms and conditions of the proposed collaboration with a third party, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

These risks and uncertainties include the following:

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

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

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

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

In addition, U.S. patent laws may change, which could prevent or limit us, our subsidiaries, or our licensors from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include the transition from a first-to-invent system to a first-to-file system and changes to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents.

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

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

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

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

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

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of August 5, 2024, we had 300 employees. To manage our anticipated future growth and focus in neurology and immunology, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these activities. Due to our limited resources, we may not be able to effectively manage the expansion and shift of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our transition to a strategy primarily focused on neurology and immunology, our expenses may increase more than expected our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and changes to our business.

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

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

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

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, 2023, we had federal net operating loss carryforwards of approximately \$1.4 billion, and our ability to utilize those net operating loss carryforwards could be limited by an ownership change as described above, which could result in increased tax liability to us. In addition, pursuant to the Tax Act, we may not use net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed by President Trump. Certain provisions of the CARES Act alter the rules regarding net-operating losses for such losses arising in 2018, 2019 and 2020. Such losses may be carried back for five years. We cannot assure you, however, of our ability to utilize these favorable offset rules within the applicable time period. These rules apply regardless of the occurrence of an ownership change.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As another example, in August 2022, the Inflation Reduction Act of 2022 (the IRA) was enacted, and, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning after December 31, 2022. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes could adversely impact our business, results of operations and financial position. On December 14, 2023, President Biden announced that, under the IRA, dozens of pharmaceutical companies are required to pay rebates to Medicare for price hikes on prescription drugs.

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

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

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

- reception and success of BRIUMVI in the U.S. market;
- reception and success of BRIUMVI in the German market and the anticipated launch of BRIUMVI in additional European markets;
- publicity regarding actual or potential clinical results relating to our product or products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by us or our competitors;
- any delay in our regulatory review for products and product candidates we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation a change to the projected approval date, scheduling of an advisory committee meeting or issuance of a "refusal to file" letter;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- announcements of technological innovations by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments in the United States and foreign countries;
- litigation or arbitration;
- economic, political and market conditions or other crises and other external factors such as the disruptions in the global economy caused by the COVID-19 pandemic, the conflict between Russia and Ukraine, and the Israel-Hamas war;
- period-to-period fluctuations in our revenues and other results of operations;
- failure to meet our revenue projections or guidance;
- changes in financial estimates by securities analysts;
- our repurchase of shares of our common stock pursuant to our share repurchase program;
- sales of our common stock by us; and
- the occurrences of any of the risks described in this Quarterly Report.

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

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

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

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

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

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

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

In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify the existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, we cannot assure you that such insurance coverage will be sufficient to satisfy any damages and losses we may directly or indirectly incur. If the manufacturing facilities of our third-party manufacturers are unable to operate for any reason, even for a short period of time, any or all of our research and development programs or commercialization efforts may be harmed. Any material interruption could have a material and adverse effect on our business.

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. However, any future determination relating to the use of our future earnings, if any, will be made at the discretion of the Board of Directors and will depend on a number of factors, including capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that the Board of Directors may deem relevant. In addition, under the Amended Loan Agreement, as amended, 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 likely the sole source of gain for our stockholders for the foreseeable future.

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

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

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

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

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

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

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

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

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

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

If we are unable to further implement and maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods could be adversely affected, which could subject us to litigation or investigations requiring management resources and payment of legal and other expenses, negatively affect investor confidence in our financial statements and adversely impact our stock price. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

Furthermore, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could adversely affect the results of periodic management evaluations.

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

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

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

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

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

In August 2024, we announced that our Board of Directors had authorized a share repurchase program of up to \$100 million of our outstanding shares of common stock. We intend to repurchase shares of our common stock from time to time, as authorized by our Board of Directors, through open market purchases, in privately negotiated transactions or by other means, including through the use of trading plans intended to qualify under Rule 10b5-1 under the Exchange Act, in accordance with applicable securities laws and other restrictions. The timing and the amount of stock repurchases in the share repurchase program will be determined by our management, based on its evaluation of factors including business and market conditions, corporate and regulatory requirements, and other considerations. The share repurchase program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any amount of our common stock.

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

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

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

Not applicable.

ITEM 3. DEFAULTS OF SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Securities Trading Plans of Directors and Executive Officers

During the three months ended June 30, 2024, none of our directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of the Company's securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

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

3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 17, 2024).
10.1	Amendment to the TG Therapeutics, Inc. 2022 Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 17, 2024).
10.2*#	Financing Agreement between TG Therapeutics, Inc., certain subsidiaries of TG Therapeutics, Inc., various lenders from time to time party thereto, and Blue Owl Capital Corporation, dated August 2, 2024.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2024.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2024.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2024.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2024.
101*	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

** Furnished herewith.

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

SIGNATURES

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

TG THERAPEUTICS, INC.

Date: August 9, 2024

By: /s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

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 “[*]”.**

FINANCING AGREEMENT

dated as of August 2, 2024

among

**TG THERAPEUTICS, INC.,
as Borrower,**

**CERTAIN SUBSIDIARIES OF BORROWER,
as Guarantors,**

VARIOUS LENDERS FROM TIME TO TIME PARTY HERETO,

AND

**BLUE OWL CAPITAL CORPORATION,
as Administrative Agent**

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FINANCING AGREEMENT

This FINANCING AGREEMENT, dated as of August 2, 2024, is entered into by and among TG THERAPEUTICS, INC., a Delaware corporation (“Borrower”), and certain Subsidiaries of Borrower, as Guarantors, the Lenders from time to time party hereto, and Blue Owl Capital Corporation (“Blue Owl”), as administrative agent for the Lenders (in such capacity, “Administrative Agent”).

RECITALS

WHEREAS, capitalized terms used in these Recitals shall have the respective meanings set forth for such terms in Section 1.1 hereof;

WHEREAS, Lenders have agreed to extend certain senior secured credit facilities to Borrower, in an aggregate principal amount not to exceed \$350,000,000, consisting of (a) an initial term loan in an aggregate principal amount equal to \$250,000,000 and (b) an uncommitted incremental facility in an aggregate principal amount not to exceed \$100,000,000, in each case the proceeds of which will be used as described in Section 2.2;

WHEREAS, Borrower has agreed to secure all of its Obligations by granting to Administrative Agent, for the benefit of Secured Parties, a First Priority Lien on all of its assets (except as otherwise set forth in the Collateral Documents), including a pledge of all of the Capital Stock of each of its Subsidiaries (except as otherwise set forth in the Collateral Documents); and

WHEREAS, Guarantors have agreed to guarantee the Obligations of Borrower hereunder and to secure their respective Obligations by granting to Administrative Agent, for the benefit of Secured Parties, a First Priority Lien on all of their respective assets (except as otherwise set forth in the Collateral Documents), including a pledge or mortgage of all of the Capital Stock of each of their respective Subsidiaries (except as otherwise set forth in the Collateral Documents).

NOW, THEREFORE, in consideration of the premises and the agreements, provisions and covenants herein contained, the parties hereto agree as follows:

ARTICLE I

DEFINITIONS AND INTERPRETATION

Section 1.1 Definitions. The following terms used herein, including in the preamble, recitals, exhibits and schedules hereto, shall have the following meanings:

“Adjusted EBITDA” shall mean, for any period, Net Income for such period:

(a) increased, without duplication, by the following, in each case, to the extent (and in the same proportion) deducted (and not added back or excluded) in determining Net Income for such period:

- (i) consolidated interest expense of the Borrower and its Subsidiaries for such period, determined on a consolidated basis in accordance with GAAP;
 - (ii) all amounts attributable to depreciation and amortization for such period;
 - (iii) consolidated income tax expense for such period;
-

(iv) any non-cash charges or adjustments, including any equity-based or non-cash compensation charges or expenses, including any such charges or expenses arising from grants of stock appreciation or similar rights, stock options, restricted stock or other rights, retention charges (including charges or expenses in respect of incentive plans) and any write-offs or write-downs reducing Net Income for such period (*provided* that such non-cash charges do represent an accrual or reserve for potential cash items in any future period), and excluding amortization of a prepaid cash item that was paid in a prior period;

(v) the amount of restructuring charges or any reasonable and documented out-of-pocket costs, fees or expenses incurred in connection with any Permitted Acquisitions or other similar Permitted Investment, any permitted issuance of Capital Stock or Indebtedness or any permitted Asset Sale during such period (whether or not consummated); provided, that, the aggregate amount of costs, fees, expenses, and charges added back to Adjusted EBITDA pursuant to this clause (a)(v) and clause (a)(vi), for any consecutive four Fiscal Quarter period shall not exceed the greater of (x) \$[***] and [***]% of Adjusted EBITDA (calculated prior to giving effect to this clause (a)(v) and clause (a)(vi)); and

(vi) any extraordinary, unusual, non-recurring or one-time charges, expenses or losses; provided, that, the aggregate amount of costs, fees, expenses, and charges added back to Adjusted EBITDA pursuant to this clause (a)(vi) and clause (a)(v) for any consecutive four Fiscal Quarter period shall not exceed the greater of (x) \$[***] and [***]% of Adjusted EBITDA (calculated prior to giving effect to this clause (a)(vi) and clause (a)(v)); and

(b) decreased, without duplication, and to the extent included in arriving at such Net Income:

(i) interest income for such period;

(ii) income tax credits and refunds for such period (to the extent consolidated income tax expense added-back in clause (a)(iii) above is not calculated net of such credit or refund);

(iii) non-cash gains or adjustments and all other non-cash items of income for such period; and

(iv) extraordinary, unusual, non-recurring or one-time gains or adjustments for such period.

“Administrative Agent” has the meaning specified in the preamble hereto.

“Administrative Agent’s Account” means an account at a bank designated by Administrative Agent from time to time as the account into which the Loan Parties shall make all payments to Administrative Agent under this Agreement and the other Loan Documents.

“Adverse Proceeding” means any action, suit, proceeding (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of Borrower or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims) or other regulatory body or any mediator or arbitrator, whether pending or, to the knowledge of Borrower or any of its Subsidiaries, threatened in writing against Borrower or any of its Subsidiaries or any property of Borrower or any of its Subsidiaries.

“Affected Financial Institution” means (a) any EEA Financial Institution or (b) any UK Financial Institution.

“Affected Lender” has the meaning specified in Section 2.19(b).

“Affected Loans” has the meaning specified in Section 2.19(b).

“Affiliate” means, as applied to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with, that Person. For the purposes of this definition, “control” (including, with correlative meanings, the terms “controlling,” “controlled by” and “under common control with”), as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that Person, whether through the ownership of voting securities or Capital Stock, by contract or otherwise. Notwithstanding anything herein to the contrary, in no event shall Administrative Agent or any Lender or any of their Affiliates or Related Funds be considered an “Affiliate” of any Loan Party. Any reference to an Affiliate of Blue Owl (or its Affiliates) shall include its affiliated funding entity, Hedgewig Funding I LLC, and any Person that is controlled or managed by Blue Owl (or its Affiliates), or where Blue Owl, together with its Affiliates, has a direct or indirect majority economic interest therein.

“Aggregate Amounts Due” has the meaning specified in Section 2.13.

“Aggregate Payments” has the meaning specified in Section 7.2.

“Agreement” means this Financing Agreement and any annexes, exhibits and schedules attached hereto.

“Anti-Corruption Laws” means all Requirements of Law concerning or relating to bribery or corruption, including, without limitation, the United States Foreign Corrupt Practices Act of 1977, and the anti-bribery and anti-corruption laws and regulations of those jurisdictions in which the Loan Parties do business.

“Anti-Terrorism Laws” means any Requirement of Law relating to terrorism or money laundering, including, without limitation, (a) the Money Laundering Control Act of 1986 (18 U.S.C. §§ 1956 and 1957), (b) the Currency and Foreign Transactions Reporting Act (31 U.S.C. §§ 5311-5330 and 12 U.S.C. §§ 1818(s), 1820(b) and 1951-1959) (the “Bank Secrecy Act”), (c) the USA PATRIOT Act, (d) the laws, regulations and Executive Orders administered by the United States Department of the Treasury’s Office of Foreign Assets Control (“OFAC”), (e) the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 and implementing regulations by the United States Department of the Treasury, (f) any law prohibiting or directed against terrorist activities or the financing of terrorist activities (*e.g.*, 18 U.S.C. §§ 2339A and 2339B), or (g) any similar laws enacted in the United States or any other jurisdictions in which the parties to this Agreement operate, as any of the foregoing laws may from time to time be amended, renewed, extended, or replaced and all other present and future legal requirements of any Governmental Authority governing, addressing, relating to, or attempting to eliminate, terrorist acts and acts of war and any regulations promulgated pursuant thereto.

“Applicable Margin” means, as of any date of determination with respect to any Term Loan, the applicable percentage per annum set forth in the table below that corresponds to the most recent US Net Sales Calculation:

Pricing Level	US Net Sales for the most recent Measurement Period	Applicable Margin for SOFR Loans	Applicable Margin for Base Rate Loans
I	Less than \$[***]	5.50%	4.50%
II	Greater than or equal to \$[***]	5.25%	4.25%

Any adjustment to the Applicable Margin shall be re-determined quarterly as of the [***] immediately following the date of delivery (or required delivery) to the Administrative Agent of the US Net Sales Calculation (each, a “Pricing Adjustment Date”); *provided* that, if the Borrower fails to provide such certification when such certification is due, the Applicable Margin shall be set at the margin in the row styled “Level I” in the tables above, effective as of the immediately succeeding Pricing Adjustment Date until the date on which such certification is delivered (on which date (but not retroactively), without constituting a waiver of any Default or Event of Default occasioned by the failure to timely deliver such certification, the Applicable Margin shall be set at the rate based upon the US Net Sales Calculation set forth in such certification).

“Applicable Premium” has the meaning specified in the Fee Letter.

“Application Event” means the (a) occurrence of an Event of Default and (b) the election by Administrative Agent or the Required Lenders during the continuance of such Event of Default to require that payments and proceeds of Collateral be applied pursuant to Section 2.12(f).

[***]

[***]

“Asset Sale” means a sale, lease or sublease (as lessor or sublessor), sale and leaseback, assignment, conveyance, transfer, license or sublicense or other disposition to, or any exchange of property with, any Person (other than to a Loan Party), in one transaction or a series of transactions, of all or any part of any Loan Party’s businesses, assets or properties of any kind, whether real, personal, or mixed and whether tangible or intangible, whether now owned or hereafter acquired, including, without limitation, the Capital Stock of any Loan Party. For purposes of clarification, “Asset Sale” shall include (a) the sale or other disposition for value of any contracts, (b) any disposition of property through a “plan of division” under the Delaware Limited Liability Company Act or any comparable transaction under any similar law, (c) any sale of accounts (or any rights thereto (including, without limitation, any rights to any residual payment stream with respect thereto)) by any Loan Party or Subsidiary of Borrower, (d) any Product Agreement, (e) any Permitted Product Transaction and (f) any Royalty Monetization Transaction.

Notwithstanding the foregoing, none of the following items will be deemed to be an Asset Sale:

- (i) an issuance of Capital Stock by a Subsidiary of Borrower to Borrower or to another Loan Party;
- (ii) an issuance of Capital Stock by Borrower;
- (iii) use or transfer of Cash or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; and

(iv) the non-exclusive licensing or sublicensing alone of any Intellectual Property Rights in the ordinary course of business that does not materially interfere with the ordinary conduct of the business of Borrower or any of its Subsidiaries and that is otherwise permitted under this Agreement (provided and for the avoidance of doubt that (x) any exclusive or co-exclusive out-license with respect to any Intellectual Property Rights, (y) any Permitted Product Transaction and (y) any Royalty Monetization Transaction, in each case (as applicable) shall be deemed to be an Asset Sale).

“Assignment Agreement” means an Assignment and Assumption Agreement substantially in the form of Exhibit C, with such amendments or modifications as may be approved by Administrative Agent.

“Authorized Officer” means, as applied to any Person, any individual holding the position of chairman of the board (if an officer), director, chief executive officer, president or one of its vice presidents (or the equivalent thereof), and such Person’s chief financial officer or treasurer.

“Available Tenor” means, as of any date of determination and with respect to the then-current Benchmark, as applicable, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component thereof) that is or may be used for determining the length of an interest period pursuant to this Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then-removed from the definition of “Interest Period” pursuant to Section 2.20(d).

“Bail-in Action” means the exercise of any Write-Down and Conversion Powers by the applicable Resolution Authority in respect of any liability of an Affected Financial Institution.

“Bail-In Legislation” means (a) with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law, regulation, rule or requirement for such EEA Member Country from time to time that is described in the EU Bail-In Legislation Schedule and (b) with respect to the United Kingdom, Part I of the United Kingdom Banking Act 2009 (as amended from time to time) and any other law, regulation or rule applicable in the United Kingdom relating to the resolution of unsound or failing banks, investment firms or other financial institutions or their affiliates (other than through liquidation, administration or other insolvency proceedings).

“Bank Secrecy Act” has the meaning specified in the definition of “Anti-Terrorism Laws”.

“Bankruptcy Code” means Title 11 of the United States Code entitled “Bankruptcy,” as now and hereafter in effect, or any successor statute.

“Base Rate” means, for any day, a rate per annum equal to the greatest of (a) the Prime Rate in effect on such day, (b) the Federal Funds Effective Rate in effect on such day plus ½ of 1%, (c) Term SOFR (which rate shall be calculated based upon an Interest Period of three months and to be determined on a daily basis) plus 1.00%, and (d) 2.00% per annum. Any change in the Prime Rate, the Federal Funds Effective Rate or Term SOFR shall be effective on the effective day of such change in the Prime Rate, the Federal Funds Effective Rate or Term SOFR, respectively.

“Base Rate Loan” means a Loan bearing interest at a rate determined by reference to the Base Rate.

“Base Rate Term SOFR Determination Day” has the meaning specified in the definition of “Term SOFR”.

“Benchmark” means, initially, Term SOFR; provided that if a Benchmark Transition Event has occurred with respect to Term SOFR or the then-current Benchmark, then “Benchmark” means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.20(a).

“Benchmark Replacement” means, with respect to any Benchmark Transition Event, the sum of: (a) the alternate benchmark rate that has been selected by Administrative Agent in consultation with Borrower giving due consideration to (i) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a benchmark rate as a replacement for the then-current Benchmark for Dollar-denominated syndicated credit facilities at such time and (b) the related Benchmark Replacement Adjustment; provided that if such Benchmark Replacement as so determined (including any related Benchmark Replacement Adjustment) would be less than the Floor, such Benchmark Replacement shall be deemed to be the Floor for the purposes of this Agreement and the other Loan Documents.

“Benchmark Replacement Adjustment” means, with respect to any replacement of the then-current Benchmark with an Unadjusted Benchmark Replacement, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been reasonably selected by the Administrative Agent in consultation with Borrower giving due consideration to (a) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement by the Relevant Governmental Body or (b) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement for Dollar-denominated syndicated credit facilities at such time.

“Benchmark Replacement Date” means the earliest to occur of the following events with respect to the then-current Benchmark:

(a) in the case of clause (a) or (b) of the definition of “Benchmark Transition Event,” the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); or

(b) in the case of clause (c) of the definition of “Benchmark Transition Event,” the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be non-representative; provided that such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c), and even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date.

For the avoidance of doubt, the “Benchmark Replacement Date” will be deemed to have occurred in the case of clause (a) or (b) with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then-current Available Tenors of such Benchmark (or the published component used in the calculation thereof).

“Benchmark Transition Event” means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof);

(b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Board of Governors, the Federal Reserve Bank of New York, an insolvency official with jurisdiction over the administrator for such Benchmark (or such component), a resolution authority with jurisdiction over the administrator for such Benchmark (or such component) or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark (or such component), which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or

(c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are not, or as of a specified future date will not be, representative.

For the avoidance of doubt, a “Benchmark Transition Event” will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof).

“Benchmark Transition Start Date” means, in the case of a Benchmark Transition Event, the earlier of (a) the applicable Benchmark Replacement Date and (b) if such Benchmark Transition Event is a public statement or publication of information of a prospective event, the 90th day prior to the expected date of such event as of such public statement or publication of information (or if the expected date of such prospective event is fewer than 90 days after such statement or publication, the date of such statement or publication).

“Benchmark Unavailability Period” means the period (if any) (x) beginning at the time that a Benchmark Replacement Date has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.20 and (y) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.20.

“Beneficiary” means Administrative Agent and each Lender.

“Benefit Plan” means any of (a) an “employee benefit plan” (as defined in Section 3(3) of ERISA) that is subject to Title I of ERISA, (b) a “plan” as defined in Section 4975 of the Internal Revenue Code to which Section 4975 of the Internal Revenue Code applies, and (c) any Person whose assets include (for purposes of the Plan Asset Regulations or otherwise for purposes of Title I of ERISA or Section 4975 of the Internal Revenue Code) the assets of any such “employee benefit plan” or “plan”.

“Blocked Person” means any Person: (a) that is publicly identified (i) on the most current list of “Specially Designated Nationals and Blocked Persons” published by OFAC or resides, is organized or chartered, or has a place of business in a country or territory subject to an OFAC comprehensive sanctions or embargo program (as of the date of this Agreement, Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, and the so-called Donetsk People’s Republic (DNR) and Luhansk People’s Republic (LNR) regions of Ukraine) or (ii) that is prohibited from doing business with the United States under the International Emergency Economic Powers Act, the Trading With the Enemy Act, or any other Anti-Terrorism Law; (b) that is owned 50.0% or more or controlled by or that is acting for or on behalf of, any Person described in clause (a) above; and (c) that any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law.

“Blue Owl” has the meaning specified in the preamble hereto.

“Board of Directors” means, (a) with respect to any corporation or company, the board of directors of the corporation, company or any committee thereof duly authorized to act on behalf of such board, (b) with respect to a partnership, the board of directors of the general partner of the partnership, (c) with respect to a limited liability company, the managing member or members or any controlling committee or board of directors of such company or the sole member or the managing member thereof, and (d) with respect to any other Person, the board or committee of such Person serving a similar function.

“Borrower” has the meaning specified in the preamble hereto.

“BRIUMVI” means any product containing, whether alone or with any other active ingredient, (a) Borrower’s and its Subsidiaries’ anti-CD20 monoclonal antibody known as BRIUMVI™ (formerly known as ublituximab-xiiy), the sequence of which is set forth on Schedule 1.1(a) hereto, (b) antibodies or binding agents comprising the CDR sequences set forth on Schedule 1.1(a) hereto, (c) antigen-binding fragments of the product of preceding clauses (a) or (b), (d) antibodies or binding agents incorporating one or more antigen-binding fragments of the preceding clauses (a), (b) or (c), and (e) all forms, presentations, formulations or dosage forms of the product described in the preceding clauses (a), (b), (c), or (d).

“BRIUMVI License Agreement” means that certain Exclusive License Agreement, dated as of January 30, 2012 by and among, GTC Biotherapeutics, Inc., LFB Biotechnologies, S.A.S. (“LFB”), LFB/GTC LLC and Borrower, as amended by Amendment No. 1 to Schedule 4 of the Exclusive License Agreement dated as of August 16, 2022, Amendment to Section 2.2.1 of Exclusive License Agreement dated as of June 30, 2023 and Amendment to Section 5.3 of Exclusive License Agreement dated as of June 30, 2023, and as may be further amended, restated or otherwise modified from time to time to the extent permitted hereunder.

“Business Day” means any day that is not a Saturday, Sunday, or any other day on which the Federal Reserve Bank of New York is closed.

“Capital Lease” means, as applied to any Person, any lease of any property (whether real, personal or mixed) by that Person (a) as lessee that, in conformity with GAAP, is or should be accounted for as a capital lease on the balance sheet of that Person or (b) as lessee that is a transaction of a type commonly known as a “synthetic lease” (i.e., a transaction that is treated as an operating lease for accounting purposes but with respect to which payments of rent are intended to be treated as payments of principal and interest on a loan for income tax purposes).

“Capital Stock” means any and all shares, interests, participations or other equivalents (however designated) of capital stock of a company or a corporation, any and all equivalent ownership interests in a Person (other than a corporation), including, without limitation, shares, partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire any of the foregoing; provided that Capital Stock shall exclude debt securities and other Indebtedness convertible into or exchangeable for any of the foregoing (including without limitation, Permitted Convertible Indebtedness).

“Cash” means money, currency or a credit balance in any demand or Deposit Account.

“Cash Equivalents” means, as at any date of determination, (a) marketable securities (i) issued or directly and unconditionally guaranteed as to interest and principal by the United States Government, or (ii) issued by any agency of the United States the obligations of which are backed by the full faith and credit of the United States, in each case maturing within one year after such date, (b) marketable direct obligations issued by any state of the United States of America or any political subdivision of any such state or any public instrumentality thereof, in each case maturing within one year after such date and having, at the time of the acquisition thereof, a rating of at least A 1 from S&P or at least P 1 from Moody’s, (c) commercial paper maturing no more than one year from the date of creation thereof and having, at the time of the acquisition thereof, a rating of at least A 1 from S&P or at least P 1 from Moody’s, (d) certificates of deposit or bankers’ acceptances maturing within one year after such date and issued or accepted by any Lender or by any commercial bank organized under the laws of the United States of America or any state thereof or the District of Columbia that (i) is at least “adequately capitalized” (as defined in the regulations of its primary Federal banking regulator), and (ii) has Tier 1 capital (as defined in such regulations) of not less than \$100,000,000, and (e) shares of any money market mutual fund that (i) has substantially all of its assets invested continuously in the types of investments referred to in clauses (a) and (b) above, (ii) has net assets of not less than \$500,000,000, and (iii) has the highest rating obtainable from either S&P or Moody’s.

“Change of Control” means, at any time, any of the following occurrences:

(a) any Person or “group” (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) (i) shall have acquired beneficial ownership of 35% or more on a fully diluted basis of the voting or economic interest in the securities or Capital Stock of Borrower or (ii) shall have obtained the power (whether or not exercised) to elect a majority of the members of the Board of Directors (or similar governing body) of Borrower; provided that for purposes of this provision, any Person or group shall not be deemed to beneficially own Capital Stock to be acquired by such Person or group pursuant to a stock or asset purchase agreement, merger agreement, option agreement, warrant agreement or similar agreement (or voting or option or similar agreement related thereto) until the consummation of the acquisition of the Capital Stock in connection with the transactions contemplated;

(b) any “change of control”, “fundamental change” or similar event shall occur under, and as defined in or set forth in the documents evidencing or governing the Capital Stock of Borrower, any agreement evidencing any Royalty Monetization Transaction, any Permitted Convertible Indebtedness or any other Indebtedness in an aggregate principal amount of \$10,000,000 or more of Borrower or any of its Subsidiaries, in each case to the extent any repayment or payment obligation would result in connection with the occurrence of such event; or

(c) Borrower shall cease to beneficially own and control 100% on a fully diluted basis of the economic and voting interest in the Capital Stock of each other Loan Party free and clear of any Lien other than the Lien granted to the Administrative Agent for the benefit of the Secured Parties.

“Closing Date” means the date on which this Agreement becomes effective, which is August 2, 2024.

“Closing Date Certificate” means a Closing Date Certificate substantially in the form of Exhibit D.

“Closing Date Refinancing” means the repayment of all outstanding Indebtedness under that certain Loan and Security Agreement, dated as of February 28, 2019, by and among the Borrower, certain of the Borrower’s Subsidiaries, the several banks and other financial institutions or entities from time to time thereto and Hercules Capital, Inc., a Maryland corporation, as amended, and the termination of all guarantees, Liens and other security interests granted thereunder.

“Collateral” means, collectively, all of the real, personal and mixed property (including Capital Stock) and all interests therein and proceeds thereof now owned or hereafter acquired by any Loan Party upon which a Lien is granted or purported to be granted by such Loan Party in favor of the Administrative Agent pursuant to the Collateral Documents as security for the Obligations.

“Collateral Documents” means the Pledge and Security Agreement, any Control Agreement, any Mortgages and all other instruments, documents and agreements delivered by any Loan Party pursuant to this Agreement or any of the other Loan Documents in order to grant to Administrative Agent, for the benefit of Secured Parties, a Lien on any real, personal or mixed property of that Loan Party as security for the Obligations, in each case, as such Collateral Documents may be amended or otherwise modified from time to time.

“Commercialization” means any and all activities directed to the distribution, marketing, detailing, promotion, selling and securing of reimbursement of a Product (including the using, importing, selling and offering for sale of such Product), and shall include post-launch marketing, promoting, detailing, distributing, selling such Product, importing, exporting or transporting such Product for sale, and regulatory compliance with respect to the foregoing. When used as a verb, “Commercialize” shall mean to engage in Commercialization. Commercialization shall not include any activities directed to the development or manufacture of a Product.

“Common Stock” means Borrower’s common stock.

“Competing Product” means [***].

“Compliance Certificate” means a Compliance Certificate substantially in the form of Exhibit B.

“Conforming Changes” means, with respect to either the use or administration of Term SOFR or the use, administration, adoption or implementation of any Benchmark Replacement, any technical, administrative or operational changes (including changes to the definition of “Base Rate,” the definition of “Business Day,” the definition of “U.S. Government Securities Business Day,” the definition of “Interest Period” or any similar or analogous definition (or the addition of a concept of “interest period”), timing and frequency of determining rates and making payments of interest, timing of borrowing requests or prepayment, conversion or continuation notices, the applicability and length of lookback periods, the applicability of Section 2.19(c) and other technical, administrative or operational matters) that Administrative Agent, in consultation with Borrower, decides may be appropriate to reflect the adoption and implementation of any such rate or to permit the use and administration thereof by Administrative Agent in a manner substantially consistent with market practice (or, if Administrative Agent, in consultation with Borrower, decides that adoption of any portion of such market practice is not administratively feasible or if Administrative Agent, in consultation with Borrower, determines that no market practice for the administration of any such rate exists, in such other manner of administration as Administrative Agent, in consultation with Borrower, decides is reasonably necessary in connection with the administration of this Agreement and the other Loan Documents).

“Connection Income Taxes” means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

“Consolidated Total Assets” means, at any date, total assets of the Loan Parties and their Subsidiaries calculated in accordance with GAAP on a consolidated basis.

“Contractual Obligation” means, as applied to any Person, any provision of any security issued by that Person or of any indenture, mortgage, deed of trust, contract (including, but not limited to, any Material Contract), undertaking, agreement, license or other instrument to which that Person is a party or by which it or any of its properties is bound or to which it or any of its properties is subject.

“Control Agreement” means a control agreement, in form and substance reasonably satisfactory to Administrative Agent, executed and delivered by the applicable Loan Party, Administrative Agent, and the applicable securities intermediary (with respect to a Securities Account) or bank (with respect to a Deposit Account).

“Conversion/Continuation Date” means the effective date of a continuation or conversion, as the case may be, as set forth in the applicable Conversion/Continuation Notice.

“Conversion/Continuation Notice” means a Conversion/Continuation Notice substantially in the form of Exhibit A-2.

“Counterpart Agreement” means a Counterpart Agreement substantially in the form of Exhibit F delivered by a Loan Party pursuant to Section 5.10.

“Credit Date” means the date of a Credit Extension.

“Credit Extension” means the making of a Loan.

[***]

“Data” means customer lists, correspondence, data, submissions and licensing and purchasing histories relating to customers of Borrower or any Subsidiary, and all other reports, information and documentation collected or maintained by Borrower or any Subsidiary regarding purchasers of Borrower or any Subsidiary’s products and the visitors to websites owned or controlled by Borrower or any of its Subsidiaries.

“Data Protection Laws” means applicable Requirements of Law concerning the protection, privacy or security of Personal Information (including any applicable laws of jurisdictions where the Personal Information was collected or otherwise processed) and other applicable consumer protection laws, and all regulations promulgated thereunder, including, without limitation, HIPAA, the General Data Protection Regulation (and all laws implementing or supplementing it), the California Consumer Privacy Act, and Section 5 of the Federal Trade Commission Act.

“Debtor Relief Law” means the Bankruptcy Code and any other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief law of the United States or other applicable jurisdiction from time to time in effect.

“Default” means a condition or event that, after notice or lapse of time or both, would constitute an Event of Default.

“Default Excess” means, with respect to any Defaulting Lender, the excess, if any, of such Defaulting Lender’s Pro Rata Share of the aggregate outstanding principal amount of Term Loans of all Lenders (calculated as if all Defaulting Lenders (other than such Defaulting Lender) had funded all of their respective Defaulted Loans) over the aggregate outstanding principal amount of all Term Loans of such Defaulting Lender.

“Default Period” means, with respect to any Defaulting Lender, the period commencing on the date of the applicable Funding Default or violation of Section 9.5(c), as applicable, and ending on the earliest of the following dates: (a) the date on which all Term Loan Commitments are cancelled or terminated or the Obligations are declared or become immediately due and payable, (b) the date on which (i) the Default Excess with respect to such Defaulting Lender shall have been reduced to zero (whether by the funding by such Defaulting Lender of any Defaulted Loans of such Defaulting Lender or by the non pro rata application of any voluntary or mandatory prepayments of the Loans in accordance with the terms of Section 2.9 or Section 2.10 or by a combination thereof), and (ii) such Defaulting Lender shall have delivered to Borrower and Administrative Agent a written reaffirmation of its intention to honor its obligations hereunder with respect to its Term Loan Commitments, (c) the date on which Borrower, Administrative Agent and Required Lenders waive all Funding Defaults of such Defaulting Lender in writing, and (d) the date on which Administrative Agent shall have waived all violations of Section 9.5(c) by such Defaulting Lender in writing.

“Default Rate” means any interest payable pursuant to Section 2.6.

“Defaulted Loan” has the meaning specified in Section 2.17.

“Defaulting Lender” has the meaning specified in Section 2.17.

“Deposit Account” means a demand, time, savings, passbook or like account with a bank, savings and loan association, credit union or like organization, other than an account evidenced by a negotiable certificate of deposit.

“Disputes” has the meaning set forth in Section 4.23(d).

“Disqualified Capital Stock” means any Capital Stock that, by its terms (or by the terms of any security or other Capital Stock into which it is convertible or for which it is exchangeable), or upon the happening of any event or condition, (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (b) is redeemable at the option of the holder thereof, in whole or in part, (c) provides for the scheduled payments of dividends or distributions in cash, or (d) is convertible into or exchangeable for (i) Indebtedness or (ii) any other Capital Stock that would constitute Disqualified Capital Stock, in each case of clauses (a) through (d), prior to the date that is [***] days after the Term Loan Maturity Date and other than solely for Qualified Capital Stock or as a result of a change of control or asset sale (so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Loans and all other Obligations that are accrued and payable and the termination of the Term Loan Commitments); provided that if such Capital Stock is issued pursuant to a plan for the benefit of current or former employees, directors, independent contractors or other service providers of the Loan Parties or by any such plan to such current or former employees, directors, independent contractors or other service providers, such Capital Stock shall not constitute Disqualified Capital Stock solely because it may be required to be repurchased by a Loan Party in order to satisfy applicable statutory or regulatory obligations, including tax withholding, or as a result of such current or former employee’s, director’s, independent contractor’s or other service provider’s termination, death or disability; provided further that Disqualified Capital Stock shall exclude Permitted Equity Derivatives.

“Disqualified Institution” means any (i) Person identified in writing to Administrative Agent prior to the Closing Date (or after the Closing Date, by written notice to the Administrative Agent, to identify any merger, name changes, business combination or transaction related to any applicable Person so as to be able to identify such Person going forward), together with any Affiliates of such Person that are (1) identified by the Borrower in writing prior to the Closing Date (or after the Closing Date, by written notice to the Administrative Agent, to identify any merger, name changes, business combination or transaction related to any applicable Person so as to be able to identify such Person going forward) or (2) clearly identifiable on the basis of such affiliate’s name and (ii) Person identified in writing by or on behalf of the Borrower to the Administrative Agent after the Closing Date if such designation is acceptable to the Administrative Agent.

“Dollars” and the sign “\$” mean the lawful money of the United States of America.

“EEA Financial Institution” means (a) any credit institution or investment firm established in any EEA Member Country that is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country that is a parent of an institution described in clause (a) of this definition, or (c) any financial institution established in an EEA Member Country that is a subsidiary of an institution described in clauses (a) or (b) of this definition and is subject to consolidated supervision with its parent.

“EEA Member Country” means any of the member states of the European Union, Iceland, Liechtenstein, and Norway.

“EEA Resolution Authority” means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

“Eligible Assignee” means (a) any Lender, any Affiliate of any Lender and any Related Fund (any two or more Related Funds being treated as a single Eligible Assignee for all purposes hereof), (b) any commercial bank, insurance company, investment or mutual fund or other entity that is an “accredited investor” (as defined in Regulation D under the Securities Act) and which extends credit or buys loans as one of its businesses, and (c) any other Person (other than a natural Person); provided, that neither Borrower nor any Affiliate of Borrower shall, in any event, be an Eligible Assignee.

“EMA” means the European Medicines Agency, or any successor agency thereto.

“Employee Benefit Plan” means any “employee benefit plan” as defined in Section 3(3) of ERISA that is or was sponsored, maintained or contributed to by, or required to be contributed by, Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates.

“Environmental Claim” means any complaint, summons, citation, investigation, notice, directive, notice of violation, order, claim, demand, action, litigation, judicial or administrative proceeding, judgment, letter or other communication from any Governmental Authority or any other Person, involving (a) any actual or alleged violation of any Environmental Law, (b) any Hazardous Material or any actual or alleged Hazardous Materials Activity, (c) injury to the environment, natural resource, any Person (including wrongful death) or property (real or personal) in connection with Hazardous Materials or actual or alleged violations of Environmental Laws, or (d) actual or alleged Releases or threatened Releases of Hazardous Materials either (i) on, at or migrating from any assets, properties or businesses currently or formerly owned or operated by any Loan Party or any of its Subsidiaries or any predecessor in interest, (ii) from adjoining properties or businesses, or (iii) onto any facilities that received Hazardous Materials generated by any Loan Party or any of its Subsidiaries or any predecessor in interest.

“Environmental Laws” means any and all current or future foreign or domestic, federal or state (or any subdivision of either of them), statutes, ordinances, orders, rules, regulations, judgments, decrees, permits, licenses or binding determinations of any Governmental Authorizations, or any other requirements of Governmental Authorities relating to (a) the manufacture, generation, use, storage, transportation, treatment, disposal or Release of Hazardous Materials, or (b) occupational safety and health, industrial hygiene, land use or the protection of the environment, human, plant or animal health or welfare.

“Environmental Liabilities and Costs” means all liabilities, monetary obligations, losses (including monies paid in settlement), damages, punitive damages, natural resources damages, consequential damages, treble damages, costs and expenses (including all reasonable fees, disbursements and expenses of counsel, experts and consultants and costs of investigations and feasibility studies), fines, penalties, sanctions and interest incurred in connection with any Remedial Action, any Environmental Claim, or any other claim or demand by any Governmental Authority or any Person that relates to any actual or alleged violation of Environmental Laws, actual or alleged exposure or threatened exposure to Hazardous Materials, or any actual or alleged Release or threatened Release of Hazardous Materials.

“Environmental Lien” means any Lien in favor of any Governmental Authority for Environmental Liabilities and Costs.

“ERISA” means the Employee Retirement Income Security Act of 1974.

“ERISA Affiliate” means, as applied to any Person, (a) any corporation that is a member of a controlled group of corporations within the meaning of Section 414(b) of the Internal Revenue Code of which that Person is a member; (b) any trade or business (whether or not incorporated) that is a member of a group of trades or businesses under common control within the meaning of Section 414(c) of the Internal Revenue Code of which that Person is a member; and (c) any member of an affiliated service group within the meaning of Section 414(m) or (o) of the Internal Revenue Code of which that Person, any corporation described in clause (a) above or any trade or business described in clause (b) above is a member. Any former ERISA Affiliate of Borrower or any of its Subsidiaries shall continue to be considered an ERISA Affiliate of Borrower or any such Subsidiary within the meaning of this definition with respect to the period such entity was an ERISA Affiliate of Borrower or such Subsidiary and with respect to liabilities arising after such period for which Borrower or such Subsidiary would be liable under the Internal Revenue Code or ERISA.

“ERISA Event” means (a) a “reportable event” within the meaning of Section 4043 of ERISA and the regulations issued thereunder with respect to any Pension Plan (excluding those for which the provision for thirty day notice to the PBGC has been waived by regulation), (b) the failure to meet the minimum funding standard of Section 412 of the Internal Revenue Code with respect to any Pension Plan (whether or not waived in accordance with Section 412(c) of the Internal Revenue Code) or the failure to make by its due date a required installment under Section 430 of the Internal Revenue Code with respect to any Pension Plan or the failure to make any required contribution to a Multiemployer Plan, (c) the provision by the administrator of any Pension Plan pursuant to Section 4041(a)(2) of ERISA of a notice of intent to terminate such plan in a distress termination described in Section 4041(c) of ERISA, (d) the withdrawal by Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates from any Pension Plan with two or more contributing sponsors or the termination of any such Pension Plan resulting in liability to Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates pursuant to Section 4063 or 4064 of ERISA, (e) the institution by the PBGC of proceedings to terminate any Pension Plan, or the occurrence of any event or condition that might constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Pension Plan, (f) the imposition of a liability on Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates pursuant to Section 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA, (g) the withdrawal of Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates in a complete or partial withdrawal (within the meaning of Sections 4203 and 4205 of ERISA) from any Multiemployer Plan if there is any potential material liability therefor, or the receipt by Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates of notice from any Multiemployer Plan that it is in insolvency pursuant to Section 4245 of ERISA, or that it intends to terminate or has terminated under Section 4041A or 4042 of ERISA, (h) the occurrence of an act or omission that would reasonably be expected to give rise to the imposition on Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates of fines, penalties, taxes or related charges under Chapter 43 of the Internal Revenue Code or under Section 502(c), (i) or (l), of ERISA in respect of any Employee Benefit Plan, (i) the assertion of a material claim (other than routine claims for benefits) against any Employee Benefit Plan other than a Multiemployer Plan or the assets thereof, or against Borrower, any of its Subsidiaries or any of their respective ERISA Affiliates in connection with any Employee Benefit Plan, (j) receipt from the Internal Revenue Service of notice of the failure of any Pension Plan (or any other Employee Benefit Plan intended to be qualified under Section 401(a) of the Internal Revenue Code) to qualify under Section 401(a) of the Internal Revenue Code, or the failure of any trust forming part of any Pension Plan to qualify for exemption from taxation under Section 501(a) of the Internal Revenue Code, (k) the imposition of a Lien pursuant to Section 430(k) of the Internal Revenue Code or pursuant to ERISA with respect to any Pension Plan; or (l) the assertion of a material claim (other than routine claims for benefits) against any Employee Benefit Plan or the assets thereof, or against Borrower, any of its Subsidiaries in connection with any Employee Benefit Plan.

“Erroneous Payment” has the meaning specified in Section 9.11(a).

“Erroneous Payment Subrogation Rights” has the meaning specified in Section 9.11(d).

“EU Bail-In Legislation Schedule” means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor person), as in effect from time to time.

“Event of Default” means each of the conditions or events set forth in Section 8.1.

“Exchange Act” means the Securities Exchange Act of 1934.

“Excluded Account” means Deposit Accounts, (a) the balance of which consists exclusively of withheld income taxes and foreign, federal, state or local employment taxes in such amounts as are required to be paid to the Internal Revenue Service or any other government agencies within the following two months with respect to employees of Borrower or any of its Subsidiaries, (b) used exclusively for payroll to or for the benefit of employees of Borrower or any of its Subsidiaries in such amounts as are required to be paid to such employees within the immediately succeeding two payroll cycles, (c) that are exclusively health care reimbursement accounts or employee benefits accounts, including any accounts exclusively containing amounts required to be paid over to an employee benefit plan pursuant to DOL Reg. Sec. 2510.3-102 on behalf of or for the benefit of employees of Borrower or any of its Subsidiaries, (d) all segregated Deposit Accounts constituting (and the balance of which consists solely of funds set aside in connection with) fiduciary accounts, escrow accounts and trust accounts, (e) any other Deposit Accounts that have amounts on deposit that do not exceed \$[***] individually or \$[***] in the aggregate at any one time, and (f) that are exclusively holding cash collateral or other deposits constituting Liens permitted by clauses (g) and (o) of Permitted Liens.

“Excluded Subsidiary” means (a) any not-for-profit Subsidiary, (b) any captive insurance entity, (c) any merger Subsidiary formed in connection with a Permitted Acquisition so long as such merger Subsidiary is merged out of existence pursuant to such Permitted Acquisition or dissolved within [***] days of its formation thereof or such later date as permitted by Administrative Agent in its reasonable discretion, (d) any Immaterial Subsidiary, and (e) any Subsidiary that is prohibited or restricted by any Requirement of Law or by contractual obligations existing on the Closing Date (or, in the case of any newly acquired Subsidiary, in existence at the time of acquisition but not entered into in contemplation thereof) from guaranteeing the Obligations or if guaranteeing the Obligations would require governmental (including regulatory) consent, approval, license or authorization, unless such consent, approval, license or authorization has been obtained. Notwithstanding the foregoing, no Subsidiary that is (i) party to any Royalty Monetization Transaction or (ii) holds material intellectual property shall be an “Excluded Subsidiary”.

“Excluded Taxes” means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or commitment hereunder pursuant to a law in effect on the date on which (i) such Lender acquires such interest in such commitment (or, in the case of Loan not funded by such Lender pursuant to a prior commitment, acquires such interest in such Loan), other than pursuant to an assignment request by the Borrower under Section 2.21(b) or (ii) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.18, amounts with respect to such Taxes were payable either to such Lender’s assignor immediately before such Lender acquired the applicable interest in such commitment or Loan (as applicable) or to such Lender immediately before it changed its lending office, (c) Taxes attributable to such Recipient’s failure to comply with Section 2.15(d), and (d) any withholding Taxes imposed under FATCA.

“Fair Share” has the meaning specified in Section 7.2.

“FASB ASC” means the Accounting Standards Codification of the Financial Accounting Standards Board.

“FATCA” means Sections 1471 through 1474 of the Internal Revenue Code, in effect as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), and any current or future regulations or official interpretations thereof and any agreements entered into pursuant to current Section 1471(b)(1) of the Internal Revenue Code (or any amended or successor version described above) and any intergovernmental agreement, treaty or convention among Governmental Authorities (and any related laws, regulations or other official administrative guidance) implementing the foregoing.

“FDA” means the U.S. Food and Drug Administration or any successor agency thereto.

“FDA Laws” means all applicable statutes, rules, regulations, orders and Requirements of Law administered, implemented, enforced or issued by FDA or any comparable Governmental Authority.

“Federal Funds Effective Rate” means for any day, the rate per annum (expressed, as a decimal, rounded upwards, if necessary, to the next higher 1/100 of 1%) equal to the weighted average of the rates on overnight Federal funds transactions with members of the Federal Reserve System arranged by Federal funds brokers on such day, as published by the Federal Reserve Bank of New York on the Business Day next succeeding such day; provided, if such day is not a Business Day, the Federal Funds Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day.

“Federal Health Care Programs” shall mean the Medicare, Medicaid and TRICARE programs and any other state or federal government health care program, as defined in 42 U.S.C. § 1320a-7b(f).

“Fee Letters” means, [***].

“Financial Officer Certification” means, with respect to the financial statements for which such certification is required, the certification of the chief financial officer of Borrower that such financial statements fairly present, in all material respects, the financial condition of Borrower and its Subsidiaries as at the dates indicated and the results of their operations and their cash flows for the periods indicated, subject to changes resulting from audit and normal year-end adjustments.

“First Priority” means, with respect to any Lien purported to be created in any Collateral pursuant to any Collateral Document, that such Lien is the only Lien to which such Collateral is subject, other than any Permitted Lien.

“Fiscal Quarter” means a fiscal quarter of any Fiscal Year.

“Fiscal Year” means the fiscal year of Borrower and its Subsidiaries ending on December 31 of each calendar year.

“Floor” means a rate of interest equal to one percent (1.00%).

“Flow of Funds Agreement” means that certain Flow of Funds Agreement, dated as of the Closing Date, duly executed by Borrower, Administrative Agent, and any other person party thereto, in form and substance reasonably satisfactory to Administrative Agent, in connection with the disbursement of Loan proceeds in accordance with Section 2.1(a)(i).

“Forecast” has the meaning specified in Section 4.8.

“Foreign Lender” means a Lender that is not a U.S. Person.

“Foreign Official” means any officer or employee of a non-U.S. government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

“Foreign Sovereign Immunities Act” means the US Foreign Sovereign Immunities Act of 1976 (28 U.S.C. Sections 1602-1611).

“Funding Default” has the meaning specified in Section 2.17.

“Funding Notice” means a written notice substantially in the form of Exhibit A-1.

“GAAP” means, subject to the limitations on the application thereof set forth in Section 1.2, United States generally accepted accounting principles in effect as of the date of determination thereof.

“Governmental Authority” means any federal, state, municipal, national, supranational or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof or any entity or officer exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, including any patent office, in each case whether associated with a state of the United States, the United States or a foreign entity or government.

“Governmental Authorization” means any permit, license, authorization, clearance, approval, Registration, plan, directive, consent order or consent decree of or from any Governmental Authority.

“Grantor” has the meaning specified in the Pledge and Security Agreement.

“Guaranteed Obligations” has the meaning specified in Section 7.1.

“Guarantor” means each Subsidiary of Borrower and each other Person that guarantees, pursuant to Article VII or otherwise, all or any part of the Obligations. For the avoidance of doubt, no Excluded Subsidiary shall be required to become a Guarantor except at the election of Borrower in accordance with Section 5.10.

“Guarantor Subsidiary” means each Guarantor.

“Guaranty” means (a) the guaranty of each Guarantor set forth in Article VII and (b) each other guaranty, in form and substance satisfactory to Administrative Agent, made by any other Guarantor for the benefit of the Secured Parties guaranteeing all or part of the Obligations.

“Hazardous Materials” means, regardless of amount or quantity, (a) any element, compound or chemical that is defined, listed or otherwise classified as a contaminant, pollutant, toxic pollutant, toxic or hazardous substance, extremely hazardous substance or chemical, hazardous waste, special waste, or solid waste under Environmental Laws or that is likely to cause immediately, or at some future time, harm to or have an adverse effect on, the environment or risk to human health or safety, including, without limitation, any pollutant, contaminant, waste, hazardous waste, toxic substance or dangerous good which is defined or identified in any Environmental Law and which is present in the environment in such quantity or state that it contravenes any Environmental Law, (b) petroleum and its refined products, (c) polychlorinated biphenyls, (d) any substance exhibiting a hazardous waste characteristic, including, without limitation, corrosivity, ignitability, toxicity or reactivity as well as any radioactive or explosive materials, (e) any raw materials, building components (including, without limitation, asbestos-containing materials) and manufactured products containing hazardous substances listed or classified as such under Environmental Laws, and (f) any substance or materials that are otherwise regulated under Environmental Law.

“Hazardous Materials Activity” means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

“HCR” means Healthcare Royalty, Inc.

“Health Care Laws” means collectively, (a) Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute); (b) Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396y (the Medicaid statute); (c) the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); (d) the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; (e) the criminal False Claims Act, 42 U.S.C. § 1320a-7b(a); (f) criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. §§ 286 and 287; (g) the criminal fraud provisions under HIPAA; (h) the Civil Monetary Penalties law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; (i) the U.S. Physician Payments Sunshine Act, 42 U.S.C. § 1320-7h; (j) the Exclusion Law, 42 U.S.C. § 1320a-7; (k) Requirements of Law regarding the collection and reporting requirements, and the processing of any applicable rebate, chargeback or adjustment, under the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government programs; (l) comparable state Requirements of Law and other Requirements of Law that directly or indirectly govern the distribution, sale or promotion of any drug or biologic; and (m) each as amended and the regulations promulgated thereunder.

“Hedging Agreement” means any interest or foreign exchange rate swap agreement, interest rate or foreign exchange cap agreement, interest rate or foreign exchange collar agreement, interest rate or foreign exchange hedging agreement or other similar agreement or arrangement, each of which is (a) for the purpose of hedging the interest rate exposure or foreign exchange exposure associated with Borrower’s and its Subsidiaries’ operations, and (b) not for speculative purposes.

“Highest Lawful Rate” means the maximum lawful interest rate, if any, that at any time or from time to time may be contracted for, charged, or received under the laws applicable to any Lender that are presently in effect or, to the extent allowed by law, under such applicable laws that may hereafter be in effect and that allow a higher maximum non-usurious interest rate than applicable laws now allow.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009), and all regulations promulgated thereunder, and other Requirements of Law regulating the privacy or security of patient-identifying health care information, including with respect to notification of breach of privacy or security of such information.

“Historical Financial Statements” means as of the Closing Date, (a) the audited financial statements of Borrower and its Subsidiaries, for the Fiscal Year ended December 31, 2023, consisting of balance sheets and the related consolidated statements of income, stockholders’ equity and cash flows for such Fiscal Year, and (b) the financial statements of Borrower and its Subsidiaries for the Fiscal Quarter ended March 31, 2024, consisting of balance sheets and the related consolidated statements of income, stockholders’ equity and cash flows for such Fiscal Quarter.

“Immaterial Subsidiary” means any Subsidiary that (i) had assets representing [***]% or less of the total assets of Borrower and its Subsidiaries, determined on a consolidated basis in accordance with GAAP, as of the last day of the most recent Fiscal Quarter for which financial statements have been, or were required to be, delivered pursuant to Section 3.1(f) or Section 5.1(b) or (c), as applicable (the “Test Date”) and (ii) contributed [***]% or less of the total revenues of Borrower and its Subsidiaries, for the Fiscal Quarter ended on the Test Date; provided, if at any time and from time to time after the Closing Date, Subsidiaries that are not Loan Parties pursuant to clause (d) of the definition of Excluded Subsidiaries comprise in the aggregate more than [***]% of the total assets of Borrower and its Subsidiaries as of the Test Date or contribute more than [***]% of the total revenues of Borrower and its Subsidiaries for the Fiscal Quarter ended on the Test Date or have Cash and Cash Equivalents in excess of [***] as of the Test Date, then Borrower shall, not later than [***] days after the date by which financial statements for such period are required to be delivered (or such longer period as the Administrative Agent may agree in its sole discretion in writing), designate in writing to Administrative Agent that one or more of such Subsidiaries is no longer an Excluded Subsidiary for purposes of this Agreement to the extent required such that the foregoing condition ceases to be true.

“Incremental Amendment” has the meaning specified in Section 2.21.

“Incremental Term Loan” has the meaning specified in Section 2.21.

“Incremental Term Loan Commitment” has the meaning specified in Section 2.21.

“Indebtedness” means, as applied to any Person, without duplication, (a) all indebtedness for borrowed money, (b) that portion of obligations with respect to Capital Leases that is properly classified as a liability on a balance sheet in conformity with GAAP, (c) all obligations of such Person evidenced by notes, bonds or similar instruments or upon which interest payments are customarily paid and all obligations in respect of notes payable and drafts accepted representing extensions of credit whether or not representing obligations for borrowed money, (d) any obligation owed for all or any part of the deferred purchase price of property or services, including any earn-outs or other deferred payment obligations in connection with an acquisition to the extent such earn-outs and deferred payment obligations are fixed and non-contingent (excluding any such obligations incurred under ERISA and excluding trade payables incurred in the ordinary course of business and repayable in accordance with customary trade terms), (e) all obligations created or arising under any conditional sale or other title retention agreement with respect to property acquired by such Person, (f) all indebtedness secured by any Lien on any property or asset owned or held by that Person regardless of whether the indebtedness secured thereby shall have been assumed by that Person or is non-recourse to the credit of that Person, (g) the face amount of any letter of credit or letter of guaranty issued, bankers’ acceptances facilities, surety bonds and similar credit transactions issued for the account of that Person or as to which that Person is otherwise liable for reimbursement of drawings, (h) the direct or indirect guaranty, endorsement (otherwise than for collection or deposit in the ordinary course of business), co-making, discounting with recourse or sale with recourse by such Person of the obligation of another, (i) any obligation of such Person the primary purpose or intent of which is to provide assurance to an obligee that the obligation of the obligor thereof will be paid or discharged, or any agreement relating thereto will be complied with, or the holders thereof will be protected (in whole or in part) against loss in respect thereof, (j) any liability of such Person for an obligation of another through any agreement (contingent or otherwise) (i) to purchase, repurchase or otherwise acquire such obligation or any security therefor, or to provide funds for the payment or discharge of such obligation (whether in the form of loans, advances, stock purchases, capital contributions or otherwise) or (ii) to maintain the solvency or any balance sheet item, level of income or financial condition of another if, in the case of any agreement described under subclauses (i) or (ii) of this clause (j), the primary purpose or intent thereof is as described in clause (i) above, (k) all obligations of such Person in respect of any exchange traded or over the counter derivative transaction, including, without limitation, any Hedging Agreement, whether entered into for hedging or speculative purposes, (l) Disqualified Capital Stock, and (m) all obligations in respect of Royalty Monetization Transactions. The Indebtedness of any Person shall include the Indebtedness of any partnership or joint venture in which such Person is a general partner or joint venturer, unless such Indebtedness is expressly non-recourse to such Person. Notwithstanding anything herein to the contrary, Indebtedness shall not include (i) prepaid or deferred revenue arising in the ordinary course of business, (ii) endorsements of checks or drafts arising in the ordinary course of business, (iii) Capital Stock to the extent not constituting Disqualified Capital Stock, (iv) any obligations in respect of any Permitted Equity Derivative, (v) deferred compensation and severance, and, solely to the extent such obligations are properly classified as liabilities on a balance sheet in conformity with GAAP, pension, retiree welfare and equivalent benefits or any deferred obligations incurred under ERISA, (vi) purchase price adjustments or earn outs or other contingent payments of a similar nature (including any non-compete payments and consulting payments) made in connection with any Investment or other acquisitions, mergers, amalgamations, or similar transaction, in each case, to the extent such obligations have not become due and payable and not been paid within 5 Business Days (unless such obligation is subject to a good faith dispute contested by appropriate proceedings) of such obligation becoming due and payable (provided that deferred payments that are fixed or not subject to a bona fide contingency shall constitute Indebtedness to the extent provided in clause (d) above), (vii) non-compete or consulting obligations incurred in connection with Investments or other acquisitions, mergers, amalgamations, or similar transaction, until such obligations become a liability on the balance sheet of such Person in accordance with GAAP, (viii) unsecured installment payments or the deferred purchase price of property or services to the extent payable solely in Qualified Capital Stock of such Person, and (ix) purchase price holdbacks in respect of a portion of the purchase price of an asset to satisfy unperformed obligations of the seller of such asset.

“Indemnified Liabilities” means, collectively, any and all liabilities (including Environmental Liabilities and Costs), obligations, losses, damages (including natural resource damages), penalties, claims (including Environmental Claims), costs (including the costs of any investigation, study, sampling, testing, abatement, cleanup, removal, remediation or other response action necessary to remove, remediate, clean up or abate any Hazardous Materials Activity), expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented out-of-pocket fees and disbursements of counsel pursuant to Sections 10.2 or 10.3 for Indemnitees in connection with any investigative, administrative or judicial proceeding commenced or threatened by any Person, whether or not any such Indemnitee shall be designated as a party or a potential party thereto, and any fees or expenses incurred by Indemnitees in enforcing this indemnity), whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations (including securities and commercial laws, statutes, rules or regulations and Environmental Laws), on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted in writing against any such Indemnitee, in any manner relating to or arising out of (a) this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including the Lenders’ agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of the Guaranty)), (b) the statements contained in the proposal letter delivered by any Lender to Borrower prior to the Closing Date with respect to the transactions contemplated by this Agreement, or (c) any Environmental Claim or any Hazardous Materials Activity relating to or arising from, directly or indirectly, any past or present activity, operation, land ownership, or practice of Borrower or any of its Subsidiaries.

“Indemnified Taxes” means all (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Loan Party under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

“Indemnitee” has the meaning specified in Section 10.3.

“Indemnitee Agent Party” has the meaning specified in Section 9.6.

“Initial Funding Date” means the Closing Date.

“Initial Term Loan” means the Term Loan funded on the Initial Funding Date pursuant to Section 2.1(a)(i).

“Insolvency Proceeding” means any proceeding commenced by or against any Person under any provision of any Debtor Relief Law.

“Intellectual Property” has the meaning specified in the Pledge and Security Agreement.

“Intellectual Property Rights” means any and all rights, title and interests in and to all intellectual property rights of every kind and nature however denominated, as they exist throughout the world, including

- (a) any Patent;

(b) trademarks, trade names, service marks, brands, trade dress and logos, packaging design, slogans, domain names and the goodwill and activities associated therewith;

(c) copyrights, mask work rights, confidential information, trade secrets, database rights, including all compilations, databases and computer programs, manuals and other documentation, and all derivatives, translations, adaptations, and combinations of the above;

(d) Know-How; and

(e) any and all other intellectual property rights or proprietary rights, whether or not patentable, including any and all registrations, applications, recordings, licenses, common-law rights, statutory rights, administrative rights, and contractual rights relating to any of the foregoing, claims of infringement and misappropriation against third parties, and regulatory filings, submissions and approvals.

“Intercompany Subordination Agreement” means that certain Intercompany Subordination Agreement, dated as of the Closing Date, made by the Loan Parties and their Subsidiaries in favor of Administrative Agent for the benefit of the Secured Parties.

“Interest Payment Date” means (a) with respect to any Base Rate Loan, the last Business Day of each Fiscal Quarter, commencing on the first such date to occur after the Closing Date, (b) with respect to any SOFR Loan, the last Business Day of each Fiscal Quarter, commencing on the first such date to occur after the Closing Date, and (c) with respect to each Loan, the final maturity date of the Loans (whether by scheduled maturity, acceleration or otherwise).

“Interest Period” means, in connection with a SOFR Loan, an interest period of three months (a) initially, commencing on the Credit Date or Conversion/Continuation Date thereof, as the case may be, and (b) thereafter, commencing on the day on which the immediately preceding Interest Period expires; provided, (i) if an Interest Period would otherwise expire on a day that is not a Business Day, such Interest Period shall expire on the next succeeding Business Day unless no further Business Day occurs in such month, in which case such Interest Period shall expire on the immediately preceding Business Day, (ii) any Interest Period that begins on the last Business Day of a calendar month (or on a day for which there is no numerically corresponding day in the calendar month at the end of such Interest Period) shall, subject to clauses (b)(iii) and (b)(iv) of this definition, end on the last Business Day of a calendar month, and (iii) no Interest Period with respect to any portion of any Term Loan shall extend beyond Term Loan Maturity Date; provided, further, that the Interest Period for any SOFR Loan to be made on the Initial Funding Date may, at the Borrower’s option, end on September 30, 2024.

“Interest Rate Determination Date” means, with respect to any Interest Period, the date that is two Business Days prior to the first day of such Interest Period.

“Internal Revenue Code” means the United States Internal Revenue Code of 1986, as amended.

“Investment” means (a) any direct or indirect purchase or other acquisition by Borrower or any of its Subsidiaries of, or of a beneficial interest in, any of the securities or Capital Stock or all or substantially all of the assets of any other Person (or of any product, division, product line or business line of such other Person), (b) any direct or indirect redemption, retirement, purchase or other acquisition for value, by any Subsidiary of Borrower from any Person, of any Capital Stock of such Person, (c) any direct or indirect loan, advance, or capital contributions (or transfer or similar payment made from one entity to its Subsidiary in lieu of any capital contributions that would otherwise be required) by Borrower or any of its Subsidiaries to any other Person, including all indebtedness (including, without limitation, any intercompany indebtedness) and accounts receivable from that other Person that are not current assets or did not arise from sales to that other Person in the ordinary course of business, and (d) any direct or indirect guarantee of any obligations of any other Person. The amount of any Investment shall be (i) the original cost of such Investment plus the cost of all additions thereto, without any adjustments for increases or decreases in value, or write ups, write downs or write offs with respect to such Investment; minus (ii) the amount of dividends or distributions actually received in connection with such Investment and any return of capital and any payment of principal received in respect of such Investment that in each case is received in cash or Cash Equivalents (not in excess of the amount of Investments originally made).

“Joint Venture” means a joint venture, partnership or other similar arrangement, whether in corporate, partnership or other legal form, in which Borrower or any of its Subsidiaries holds any Capital Stock; provided, in no event shall any corporate Subsidiary of any Person be considered to be a Joint Venture to which such Person is a party.

“Know-How” means all information and materials, including discoveries, improvements, processes, methods, protocols, formulations formulas, data (including pharmacological, toxicological, non-clinical data, clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), inventions, assays, chemical formulations, specifications, practices, procedures, technology, techniques, designs, drawings, correspondence, computer programs, documents, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority, research in progress, algorithms, data, databases, data collections, chemical and biological materials, and the results of experimentation and testing, in each case, knowledge, know-how, trade secrets and the like, in written, electronic, oral or other tangible or intangible form, patentable or otherwise, that are not generally known or otherwise in the public domain.

“Latest Maturity Date” means, as of any date of determination, the latest maturity date applicable to any Term Loan hereunder as of such date.

“Lender” means each lender listed on the signature pages hereto as a Lender, and any other Person that becomes a party hereto pursuant to an Assignment Agreement other than any Person that ceases to be a party hereto pursuant to any Assignment Agreement.

“Liabilities” means all claims, actions, suits, judgments, damages, losses, liability, obligations, responsibilities, fines, penalties, sanctions, costs, fees, taxes, commissions, charges, disbursements and expenses, in each case of any kind or nature (including interest accrued thereon or as a result thereto and fees, charges and disbursements of financial, legal and other advisors and consultants), whether joint or several, whether or not indirect, contingent, consequential, actual, punitive, treble or otherwise.

“License Agreements” has the meaning set forth in Section 4.23(b).

“Licensee” means, with respect to a Product, any third party to which Borrower or any of its Affiliates, directly or indirectly through multiple tiers, grants a license, a sublicense, or other right, in each case, to Commercialize such Product in any jurisdiction.

“Lien” means (a) any lien, mortgage, pledge, assignment, hypothec, deed of trust, security interest, license or sublicense, charge or encumbrance of any kind (including any agreement to give any of the foregoing, any conditional sale or other title retention agreement, and any lease in the nature thereof) and any option, trust or other preferential arrangement having the practical effect of any of the foregoing, and (b) in the case of securities or Capital Stock, any purchase option, call or similar right of a third party with respect to such securities or Capital Stock.

“Loan” means any Term Loan.

“Loan Account” means an account maintained hereunder by Administrative Agent on its books of account at the Payment Office, and with respect to Borrower, in which it will be charged with the Term Loan made to, and all other Obligations incurred by the Loan Parties.

“Loan Document” means any of this Agreement, the Notes, if any, the Collateral Documents, the Fee Letters, the Flow of Funds Agreement, any Guaranty, the Intercompany Subordination Agreement, the Perfection Certificate, any intercreditor agreement executed pursuant to Section 9.8(a)(ii), and all other documents, instruments or agreements executed and delivered by a Loan Party for the benefit of Administrative Agent or any Lender in connection herewith.

“Loan Party” means Borrower or any Guarantor.

“Loan Party Partner” has the meaning set forth in Section 4.33(a).

“Margin Stock” has the meaning specified in Regulation U of the Board of Governors of the Federal Reserve System as in effect from time to time.

“Market Capitalization” means, as of any date of determination, an amount equal to (a) the total number of issued and outstanding shares of Common Stock on such date, multiplied by (b) the arithmetic mean of the closing prices per share of such Common Stock on the NASDAQ exchange (or, if the primary listing of such capital stock is on another exchange, on such other exchange) for the fifteen (15) consecutive Trading Days immediately preceding such date.

“Material Adverse Effect” means a material adverse effect with respect to (a) the business operations, properties, assets, financial condition, or liabilities of Borrower and its Subsidiaries taken as a whole, (b) the ability of any Loan Party to fully and timely perform its obligations under any Loan Document to which it is a party, (c) the legality, validity, binding effect, or enforceability against a Loan Party of a Loan Document to which it is a party, (d) the validity, perfection or priority of Administrative Agent’s Liens on the Collateral or (e) the rights, remedies and benefits available to, or conferred upon, Administrative Agent and any Lender or any other Secured Party under any Loan Document.

“Material Contract” means, collectively, (i) the BRIUMVI License Agreement, (ii) the agreements listed on Schedule 1.1(b) hereto, (iii) any contract that is material to the development, manufacture or Commercialization of the Products and (iv) any other contract to which Borrower, or a Subsidiary of Borrower, as the case may be in the context in which used, is a party or any of the respective assets or properties (including, for the avoidance of doubt, the Product) of Borrower or such Subsidiary are bound or committed (other than the Loan Documents) for which any breach, violation, nonperformance or early cancellation by any party therein would have, individually or in the aggregate, a Material Adverse Effect.

“Material Jurisdiction” means as of the date of determination, each or any (as applicable) of the U.S. and such [***].

“Material Real Property” means any fee-owned real property located in the United States that is owned by any Loan Party with a fair market value in excess of \$[***] (at the time of acquisition, as reasonably estimated by the Borrower in good faith).

“Material Regulatory Liabilities” means (i) any Liabilities arising from the violation of FDA Laws, Public Health Laws, Health Care Laws, and other applicable comparable Requirements of Law, or the terms, conditions of or requirements applicable to any Registrations (including costs of actions required under applicable Requirements of Law, including FDA Laws and Health Care Laws, or necessary to remedy any violation of any terms or conditions applicable to any Registrations), including, but not limited to, withdrawal of approval or licensure, recall, revocation, suspension, import, detention and seizure of any Product, and (ii) any loss of recurring annual revenues as a result of any loss, suspension or limitation of any Registrations, that, in the case of the foregoing clauses (i) and (ii), (a) exceed \$[***] individually or \$[***] in the aggregate, or (b) could reasonably be expected to result in a Material Adverse Effect.

“Measurement Period” means, at any date of determination, the most recently completed four (4) consecutive Fiscal Quarters of the Borrower and its Subsidiaries for which financial statements have been (or were required to have been) delivered in accordance with Section 5.1(b) or 5.1(c) (or, prior to the first delivery of any such financial statements, the period of four (4) consecutive Fiscal Quarters of the Borrower and its Subsidiaries ended March 31, 2024).

“Moody’s” means Moody’s Investor Services, Inc.

“Mortgage” means a mortgage, deed of trust or deed to secure debt that encumbers Real Property, in form and substance satisfactory to Administrative Agent, made by a Loan Party in favor of Administrative Agent for the benefit of the Secured Parties, securing the Obligations and delivered to Administrative Agent.

“Multiemployer Plan” means any Employee Benefit Plan which is a “multiemployer plan” as defined in Section 3(37) of ERISA.

“Net Income” shall mean, for any period, the consolidated net income (or loss) of the Borrower and its Subsidiaries for such period, determined on a consolidated basis in accordance with GAAP.

“Net Proceeds” means (a) with respect to any Asset Sale, an amount equal to: (i) Cash payments received by Borrower or any of its Subsidiaries from such Asset Sale, minus (ii) any bona fide costs or expenses incurred in connection with such Asset Sale that are properly attributable to such Asset Sale and to the extent paid or payable to non-Affiliates, including [***], and (b) with respect to any insurance, condemnation, taking or other casualty proceeds, an amount equal to: (i) any Cash payments or proceeds received by Borrower or any of its Subsidiaries (A) under any [***] insurance policies in respect of any covered loss thereunder, or (B) as a result of the condemnation or taking of any assets of Borrower or any of its Subsidiaries by any Person pursuant to the power of eminent domain, condemnation or otherwise, or pursuant to a sale of any such assets to a purchaser with such power under threat of such a taking, minus (ii) (A) any actual costs or expenses incurred by Borrower or any of its Subsidiaries in connection with the adjustment or settlement of any claims of Borrower or such Subsidiary in respect thereof, and (B) any bona fide costs and expenses incurred in connection with any sale of such assets as referred to in clause (b)(i)(B) of this definition to the extent paid or payable to non-Affiliates, including [***], and (c) with respect to any issuance of Capital Stock, the cash proceeds thereof, net of all Taxes and customary fees, commissions, costs, underwriting discounts and other fees and expenses incurred by Borrower or any Subsidiary in connection therewith.

“NIH” has the meaning specified in the definition of Public Health Laws.

“Non-Exclusive Product Intellectual Property Rights” means any and all Intellectual Property Rights non-exclusively licensed to, or purported to be non-exclusively licensed to, Borrower or its Affiliates that are necessary for Borrower or its Affiliates to develop, manufacture or Commercialize a Product.

“Note” means a promissory note evidencing the Initial Term Loan or an Incremental Term Loan, as applicable.

“Notice” means a Funding Notice or a Conversion/Continuation Notice.

“Obligations” means all obligations of every nature of each Loan Party and its Subsidiaries from time to time owed to Administrative Agent (including former Administrative Agents), the Lenders or any of them, under any Loan Document, whether for principal, interest (including interest that, but for the filing of a petition in bankruptcy with respect to such Loan Party, would have accrued on any Obligation, whether or not a claim is allowed against such Loan Party for such interest in the related bankruptcy proceeding), the Applicable Premium, the Prepayment Premium, Erroneous Payment Subrogation Rights, fees, expenses, indemnification or otherwise and whether primary, secondary, direct, indirect, contingent, fixed or otherwise (including obligations of performance).

“OFAC” has the meaning specified in the definition of “Anti-Terrorism Laws”.

“OFAC Sanctions Programs” means (a) the Requirements of Law and Executive Orders administered by OFAC, including but not limited to, Executive Order No. 13224, and (b) the list of Specially Designated Nationals and Blocked Persons administered by OFAC, in each case, as renewed, extended, amended, or replaced.

“Organizational Documents” means (a) with respect to any corporation or company, its certificate of incorporation, its articles or memorandum of incorporation, organization or association, and its by-laws, (b) with respect to any limited partnership, its certificate of limited partnership, and its partnership agreement, (c) with respect to any general partnership, its partnership agreement, and (d) with respect to any limited liability company, its articles of organization, and its operating agreement (or, in each case of (a) through (d), the equivalent or comparable constitutive documents with respect to any non-U.S. jurisdiction). In the event any term or condition of this Agreement or any other Loan Document requires any Organizational Document to be certified by a secretary of state or similar governmental official, the reference to any such “Organizational Document” shall only be to a document of a type customarily certified by such governmental official.

“Other Connection Taxes” means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than any connection arising solely from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

“Other Taxes” has the meaning specified in Section 2.15(b).

“Participant Register” has the meaning specified in Section 10.6(h)(ii).

“Patent” means any patent or patent application, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any of the foregoing patent applications, any certificate, reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent or other governmental actions that extend the duration or any of the subject matter of a patent, and any substitution patent, confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

“PATRIOT Act” has the meaning specified in Section 4.29.

“Payment Office” means Administrative Agent’s office located at 399 Park Avenue, 38th Floor, New York, New York 10022 or such other office or offices of Administrative Agent as may be designated in writing from time to time by Administrative Agent and Borrower.

“PBGC” means the Pension Benefit Guaranty Corporation or any successor thereto.

“Pension Plan” means any Employee Benefit Plan, other than a Multiemployer Plan, that is subject to Section 412 of the Internal Revenue Code, Section 302 of ERISA or Title IV of ERISA.

“Perfection Certificate” means that certain Perfection Certificate dated as of the Closing Date.

“Periodic Term SOFR Determination Day” has the meaning specified in the definition of “Term SOFR”.

“Permitted Acquisition” means any acquisition by Borrower or its Subsidiaries, whether by purchase, merger, in-licensing or otherwise, of all or substantially all of the assets of, a majority of the Capital Stock of, or a business line or unit or a division of, or Patents, royalty rights or similar or related assets of, any Person; provided, subject to Section 1.7,

(a) immediately prior to, and after giving effect thereto, no Event of Default shall have occurred and be continuing or would result therefrom;

(b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all applicable laws and in conformity with all applicable Governmental Authorizations;

(c) in the case of the acquisition of Capital Stock, all of the Capital Stock (except for any such securities in the nature of directors’ qualifying shares required pursuant to applicable law) acquired or otherwise issued by such Person or any newly formed Guarantor Subsidiary in connection with such acquisition shall be owned 100% by a Loan Party, and Borrower shall have taken, or caused to be taken, as of the date such Person becomes a Subsidiary, any actions required to be taken as of such date as set forth in Section 5.10, Section 5.11 or Section 5.12, as applicable;

(d) Borrower and its Subsidiaries shall, on a pro forma basis after giving effect to such acquisition, as of the last day of the Fiscal Quarter most recently ended, have not less than \$[***] in Qualified Cash;

(e) in the case of an acquisition with total cash consideration in excess of \$[***], and solely to the extent reasonably available to Borrower, Borrower shall have delivered to Administrative Agent at least [***] Business Days (or such shorter period as agreed to by Administrative Agent in writing) prior to such proposed acquisition, such information and documents that Administrative Agent may reasonably request, including, without limitation, financial information with respect to such acquired assets, to the extent such financial information is available, and drafts of the respective acquisition agreements related thereto;

(f) any Person or assets or division as acquired in such Permitted Acquisition shall be in the same business or lines of business in which Borrower or its Subsidiaries are engaged as of the Closing Date (or in lines of business reasonably related or incidental thereto, or such other lines of business as may be consented to by Administrative Agent (such consent not to be unreasonably withheld or delayed));

(g) the acquisition shall have been approved by the Board of Directors or other governing body or controlling Person of the Person acquired or the Person from whom such assets or division is acquired or a court of competent jurisdiction; and

(h) the total cash consideration (excluding any portion thereof paid with the proceeds of (i) Qualified Capital Stock received no more than [***] days before such acquisition (to the extent not previously utilized for the making of any other Permitted Investment or Restricted Junior Payment), (ii) any cash consideration in connection with unsecured earnouts that by their terms are not capable of becoming due and payable prior to the date that is [***] days after the Term Loan Maturity Date or (iii) [***]) paid or payable in connection with all such acquisitions shall not exceed [***].

“Permitted Convertible Indebtedness” means Indebtedness of Borrower that is convertible based on a fixed conversion rate (subject to customary anti-dilution adjustments, “make-whole” increases and other customary changes thereto) into shares of Common Stock of Borrower (or other securities or property following a merger event or other change of the Common Stock of Borrower), cash or any combination thereof (with the amount of such cash or such combination determined by reference to the market price of such Common Stock or such other securities); provided that (a) at the time such Indebtedness is incurred, no Default or Event of Default has occurred and is continuing or would occur as a result of such incurrence, (b) all necessary corporate, company, shareholder or similar actions shall be taken and consents obtained in connection with the issuance of such Indebtedness, (c) the issuance of such Indebtedness shall be consummated in compliance with all applicable Requirements of Law, and (d) the documentation evidencing such Indebtedness shall have been delivered to Administrative Agent, together with a certificate of the chief financial officer of Borrower certifying that such Indebtedness constitutes Permitted Convertible Indebtedness, and shall be subject to customary terms for similar convertible transactions in the public markets (as determined by Borrower in good faith), including all of the following terms: (i) it shall be (and shall remain at all times) unsecured, (ii) it shall not have a scheduled maturity (and shall not have any scheduled amortization of principal) prior to the date that is [***] after the Term Loan Maturity Date in effect at the time such Indebtedness is incurred, (iii) it shall not have any covenants (including covenants relating to incurrence of Indebtedness) that are more restrictive than those set forth herein, (iv) it shall have no restrictions on Borrower’s ability to grant liens securing the Obligations, (v) it shall not prohibit the incurrence of the Obligations, (vi) it is not guaranteed by any Subsidiary, (vii) it shall bear a rate of interest similar to other comparable convertible transactions in the public markets at the time of incurrence (as determined by Borrower in good faith), and (viii) any cross-default or cross acceleration event of default (howsoever defined) provision contained therein that relates to indebtedness or other payment obligations of Borrower (or any of its Subsidiaries) (such indebtedness or other payment obligations, a “Cross-Default Reference Obligation”) contains a cure period of at least [***] calendar days (after written notice to the issuer of such Indebtedness by the trustee or to such issuer and such trustee by the requisite holders of such Indebtedness then outstanding) before a default, event of default, acceleration or other event or condition under such Cross-Default Reference Obligation results in an event of default under such cross-default or cross acceleration provision.

“Permitted Equity Derivative” means any forward purchase, accelerated share repurchase, call option, warrant or other derivative transactions in respect of Borrower’s Common Stock; provided, that (w) the terms, conditions and covenants of each such transaction shall be customary for transactions of such type, as determined by Borrower in good faith, (x) such transaction may, at the option of Borrower, be settled in Common Stock of Borrower, (y) such transaction (a) is entered into contemporaneously and otherwise in connection with the issuance of Permitted Convertible Indebtedness or (b) is explicitly permitted under Section 6.5, and (z) such transaction shall be classified in Borrower’s stockholders’ equity under FASB ASC 815-40 or any successor provision.

“Permitted Indebtedness” means:

- (a) the Obligations;
- (b) to the extent constituting Indebtedness, Permitted Intercompany Investments; provided, that such Indebtedness shall be unsecured and the parties thereto are party to an Intercompany Subordination Agreement;
- (c) Indebtedness incurred by Borrower or any of its Subsidiaries arising from agreements providing for indemnification or from guaranties or letters of credit, surety bonds or performance bonds securing the performance of Borrower or any such Subsidiary pursuant to such agreements, in connection with Permitted Acquisitions or Asset Sales permitted hereunder;
- (d) Indebtedness that may be deemed to exist pursuant to any guaranties, performance, surety, statutory, appeal or similar obligations incurred in the ordinary course of business and Indebtedness constituting guaranties in the ordinary course of business of the obligations of suppliers, customers, franchisees and licensees of Borrower and its Subsidiaries;
- (e) Indebtedness incurred in the ordinary course of business in connection with workers’ compensation, unemployment insurance and other types of social security, or to secure the performance of tenders, statutory obligations, surety and appeal bonds, bids, leases, government contracts, trade contracts, performance and return of money bonds and other similar obligations;
- (f) (i) Indebtedness in respect of netting services, overdraft protections and otherwise in connection with deposit accounts; and (ii) Indebtedness arising from the honoring by a bank or other financial institution of a check, draft or similar instrument inadvertently (except in the case of daylight overdrafts) drawn against insufficient funds in the ordinary course of business; provided, however, that such Indebtedness is extinguished within [***] of incurrence;
- (g) Indebtedness existing on the Closing Date and described in Schedule 6.1 (provided that [***]), and any Permitted Refinancing Indebtedness in respect of such Indebtedness;
- (h) Indebtedness in an aggregate amount outstanding not to exceed at any time [***] with respect to (i) Capital Leases and (ii) purchase money Indebtedness (including any Indebtedness acquired in connection with a Permitted Acquisition); provided that any such Indebtedness shall be secured only by the asset subject to such Capital Lease or by the asset acquired in connection with the incurrence of such Indebtedness;
- (i) guaranties with respect to Indebtedness of Borrower or any of its Subsidiaries, to the extent that the Person that is obligated under such guaranty could have incurred such underlying Indebtedness and to the extent such guaranties are not prohibited by Section 6.7; provided that, if the Indebtedness being guaranteed is subordinated to the Obligations, such guaranty shall be subordinated to the Obligations on terms at least as favorable to the Secured Parties as those contained in the subordination of such Indebtedness;
- (j) unsecured Indebtedness of Borrower owing to former employees, officers, or directors (or any spouses, ex-spouses, or estates of any of the foregoing) incurred in connection with the repurchase by Borrower of the Capital Stock of Borrower that has been issued to such Persons, so long as (i) no Default or Event of Default has occurred and is continuing or would result from the incurrence of such Indebtedness, (ii) the aggregate outstanding principal amount of all such Indebtedness incurred pursuant to this clause (j) does not to exceed at any time [***];

(k) Indebtedness owed to any Person providing property, casualty, liability, or other insurance to the Loan Parties, so long as the amount of such Indebtedness is not in excess of the amount of the unpaid cost of, and shall be incurred only to defer the cost of, such insurance for the period in which such Indebtedness is incurred and such Indebtedness is outstanding only during such period;

(l) adjustment of purchase price, deferred purchase price and compensation, or other similar arrangements incurred by such Person in connection with Permitted Acquisitions, any Investment permitted hereunder or any license, transfer or other Asset Sale permitted hereunder in an aggregate amount outstanding not to exceed at any time [***];

(m) Indebtedness of a Person whose assets or Capital Stock are acquired by Borrower or any of its Subsidiaries in a Permitted Acquisition; provided, that such Indebtedness (i) is either purchase money Indebtedness or a Capital Lease with respect to equipment or mortgage financing with respect to a facility, (ii) was in existence prior to the date of such Permitted Acquisition, and (iii) was not incurred in connection with, or in contemplation of, such Permitted Acquisition;

(n) Permitted Convertible Indebtedness and any Permitted Refinancing Indebtedness in respect thereof in an aggregate outstanding principal amount not to exceed at any time the greater of (i) \$[***] and (ii) the product of Borrower's Market Capitalization immediately prior to the date such Permitted Convertible Indebtedness is priced, *multiplied* by [***];

(o) Indebtedness consisting of obligations in respect of letters of credit, bank guarantees, surety bonds, performance bonds or similar extensions of credit in an aggregate outstanding principal amount not to exceed at any time \$[***];

(p) Indebtedness incurred in the ordinary course of business and owed to any financial institution in respect of (i) purchasing or credit card programs and (ii) treasury, depository or cash management services, including any payments in connection with the termination thereof;

(q) Indebtedness consisting of take-or-pay obligations contained in supply arrangements in the ordinary course of business;

(r) customer deposits and advance payments received in the ordinary course of business from customers for goods purchased in the ordinary course of business;

(s) Indebtedness incurred in connection with bankers' acceptances, discounted bills of exchange, warehouse receipts or similar facilities or the discounting or factoring of receivables for collection purposes, in each case incurred or undertaken in the ordinary course of business;

(t) guarantees incurred in the ordinary course of business in respect of obligations to suppliers, customers, franchisees, lessors, licensees, sub-licensees and distribution partners;

(u) [reserved];

(v) obligations under any Hedging Agreement;

(w) Indebtedness of non-Loan Parties and the guarantees of any such Indebtedness; provided that the aggregate principal amount or liquidation preference, as applicable, of Indebtedness incurred or guaranteed pursuant to this clause (w) at any time outstanding does not exceed \$[***]; and

- (x) other Indebtedness of Borrower and its Subsidiaries, in an aggregate amount not to exceed at any time [***];

For purposes of determining compliance with any Dollar-denominated restriction on the incurrence of Indebtedness, the Dollar equivalent principal amount of Indebtedness denominated in a foreign currency shall be calculated based on the relevant currency exchange rate in effect on the date such Indebtedness was incurred, in the case of term debt, or first committed, in the case of revolving credit debt.

“Permitted Intercompany Investments” means Investments by (a) a Loan Party to or in another Loan Party, (b) a Subsidiary that is an Excluded Subsidiary to or in another Subsidiary that is an Excluded Subsidiary, (c) a Subsidiary that is an Excluded Subsidiary to or in a Loan Party, so long as, in the case of a loan or an advance, the parties thereto are party to an Intercompany Subordination Agreement, (d) Investments by the Loan Parties in Subsidiaries that are not Loan Parties to the extent such Investments constitute bona fide transfer pricing transactions, cost-sharing arrangements or “cost-plus” arrangements in the ordinary course of business; and (e) additional Investments by the Loan Parties in Subsidiaries that are not Loan Parties in an aggregate amount outstanding not to exceed at any time \$[***]; provided that, (i) no Product or Product Intellectual Property Rights shall be assigned, transferred, contributed, licensed, sublicensed, or otherwise disposed by any Loan Party pursuant to this clause (e) and (ii) no Investment otherwise permitted by this clause (e) shall be made during the Restricted Period.

“Permitted Investments” means:

- (a) Investments in Cash and Cash Equivalents;
- (b) Investments owned as of the Closing Date in any Subsidiary and equity Investments in an aggregate amount outstanding not to exceed at any time \$[***] owned as a result of the formation of a Subsidiary to the extent otherwise permitted hereunder;
- (c) Permitted Intercompany Investments;
- (d) loans and advances to employees of Borrower and its Subsidiaries (i) made in the ordinary course of business, existing on the Closing Date and described on Schedule 6.6, and (ii) any refinancings of such loans after the Closing Date in an aggregate amount not to exceed \$[***] at any time outstanding;
- (e) Permitted Acquisitions;
- (f) Investments existing on the Closing Date and described in Schedule 6.7; provided that [***];
- (g) any Investments consisting of extensions of credit in the nature of accounts receivable or notes receivable arising from the grant of trade credit in the ordinary course of business or received in compromise or resolution of (i) obligations of trade creditors or customers that were incurred in the ordinary course of business of Borrower or any of its Subsidiaries, including pursuant to any plan of reorganization or similar arrangement upon the bankruptcy or insolvency of any trade creditor or customer or (ii) litigation, arbitration or other disputes;
- (h) Investments in negotiable instruments deposited or to be deposited for collection in the ordinary course of business;
- (i) Investments in the ordinary course of business consisting of customary trade arrangements with customers;

- (j) advances made in connection with purchases of goods or services in the ordinary course of business;
- (k) Investments held by a Person acquired in a Permitted Acquisition to the extent that such Investments were not made in contemplation of or in connection with such Permitted Acquisition and were in existence on the date of such Permitted Acquisition;
 - (l) so long as no Event of Default has occurred and is continuing or would result therefrom, Investments in Joint Ventures in an aggregate outstanding amount not to exceed [***];
- (m) Permitted Equity Derivatives;
- (n) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of suppliers and customers and in settlement of delinquent obligations of, and other disputes with, customers and suppliers arising in the ordinary course of business;
- (o) Investments under Hedging Agreement permitted under this Agreement;
- (p) any Investment of the non-cash consideration received from an Asset Sale that was made pursuant to and in compliance with this Agreement;
- (q) Investments consisting of earnest money deposits made by the Borrower or its Subsidiaries in connection with any letter of intent or other agreement in respect of any Investment permitted by this Agreement;
- (r) acquisitions of obligations of one or more officers or other employees of Borrower or any Subsidiary of the Borrower in connection with such officer's or employee's acquisition of Capital Stock of any direct or indirect parent of the Borrower, so long as no cash is actually advanced by the Borrower or any Subsidiary to such officers or employees in connection with the acquisition of any such obligations;
- (s) guarantees of operating leases or of other obligations, in each case, that do not constitute Indebtedness, and are entered into by the Borrower or any Subsidiary in the ordinary course of business;
- (t) Investments consisting of the redemption, purchase, repurchase or retirement of any Capital Stock of Borrower permitted by this Agreement;
- (u) so long as no Default or Event of Default has occurred and is continuing or would result therefrom, Investments made with Capital Stock (other than Disqualified Capital Stock) of the Borrower or from the Net Proceeds received by the Borrower from the sale of Capital Stock of the Borrower so long as (i) such Investments are made within [***] days after the receipt of such proceeds and (ii) such proceeds have not otherwise been utilized for the making of any Permitted Acquisition or Restricted Junior Payment; and
- (v) so long as no Default or Event of Default has occurred and is continuing or would result therefrom, other Investments in an aggregate amount outstanding not to exceed at any time [***].

Notwithstanding anything to the contrary contained herein, at no time during a Restricted Period shall any Investment otherwise permitted under the foregoing clauses (d)(ii), (e), (l), (m), (o), (u) or (v) be made.

“Permitted Liens” means:

- (a) Liens in favor of Administrative Agent for the benefit of Secured Parties granted pursuant to any Loan Document;
- (b) Liens for Taxes (i) not yet due and payable or (ii) if obligations with respect to such Taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted and reserves required by GAAP have been made;
- (c) statutory Liens of landlords, banks (and rights of set off), of carriers, warehousemen, mechanics, repairmen, workmen and materialmen, and other Liens imposed by law (other than any such Lien imposed pursuant to Section 430(k) of the Internal Revenue Code or by ERISA), in each case incurred in the ordinary course of business for amounts not yet overdue;
- (d) Liens incurred in the ordinary course of business in connection with workers’ compensation, unemployment insurance and other types of social security, or to secure the performance of tenders, statutory obligations, surety and appeal bonds, bids, leases, government contracts, trade contracts, performance and return of money bonds and other similar obligations (exclusive of obligations for the payment of borrowed money or other Indebtedness), so long as no foreclosure, sale or similar proceedings have been commenced with respect to any portion of the Collateral on account thereof;
- (e) easements, rights of way, restrictions, encroachments, and other minor defects or irregularities in title, in each case, that do not and will not interfere in any material respect with the ordinary conduct of the business of Borrower or any of its Subsidiaries;
- (f) any interest or title of a lessor or sublessor under any lease of real estate permitted hereunder;
- (g) Liens solely on any cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any letter of intent or purchase agreement permitted hereunder;
- (h) purported Liens evidenced by the filing of precautionary UCC financing statements relating solely to operating leases of personal property entered into in the ordinary course of business;
- (i) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods;
- (j) any zoning or similar law or right reserved to or vested in any governmental office or agency to control or regulate the use of any real property;
- (k) Liens existing on the Closing Date and described in Schedule 6.2; provided that [***]; provided, further that any such Lien shall only secure the Indebtedness that it secures on the Closing Date and any Permitted Refinancing Indebtedness in respect thereof;
- (l) Liens securing Capital Leases or purchase money Indebtedness permitted pursuant to clause (h) of the definition of Permitted Indebtedness; provided, any such Lien shall encumber only the asset subject to such Capital Lease or the asset acquired with the proceeds of such Indebtedness;
- (m) Liens granted in the ordinary course of business on the unearned portion of insurance premiums securing the financing of insurance premiums to the extent the financing is permitted under the definition of Permitted Indebtedness;

(n) Liens assumed by Borrower and its Subsidiaries in connection with a Permitted Acquisition that secure Indebtedness permitted by clause (m) of the definition of Permitted Indebtedness;

(o) (i) Liens solely on any cash deposits securing Indebtedness permitted pursuant to clause (o) of the definition of Permitted Indebtedness not in excess of [***]% of the face amount of such Indebtedness secured thereby, (ii) Liens on cash deposits not exceeding \$[***] in the aggregate securing Indebtedness permitted pursuant to clause (p)(i) of the definition of Permitted Indebtedness, and (iii) Liens granted in the ordinary course of business on cash deposits securing Indebtedness permitted pursuant to clause (p)(ii) of the definition of Permitted Indebtedness;

(p) Liens in favor of vendors or suppliers of such Person in the ordinary course of business to the extent encumbering property purchased from or provided by such vendors or suppliers and the proceeds thereof;

(q) Liens securing any judgments, writs or warrants of attachment or similar process not constituting an Event of Default under Section 8.1(h);

(r) leases, subleases, licenses or sublicenses that are (i) permitted by Section 6.9(b) or (ii) excluded from the definition of Asset Sale;

(s) bankers' Liens, rights of setoff and other similar Liens existing solely with respect to cash and Cash Equivalents on deposit in one or more accounts maintained by Borrower or its Subsidiaries, in each case granted in the ordinary course of business in favor of the bank or banks with which such accounts are maintained, securing amounts owing to such bank with respect to cash management and operating account arrangements, including those involving pooled accounts and netting arrangements, as part of a bank's standard term and conditions; provided, that, unless such Liens are non-consensual and arise by operation of law, in no case shall any such Liens secure (either directly or indirectly) the repayment of any Indebtedness;

(t) Liens (i) of a collection bank arising under Section 4-210 of the UCC, or any comparable or successor provision, on items in the course of collection; and (ii) in favor of banking or other financial institutions or entities, or electronic payment service providers, arising as a matter of law encumbering deposits (including the right of set-off) and that are within the general parameters customary in the banking or finance industry;

(u) [reserved];

(v) Liens on specific items of inventory or other goods and proceeds of the Borrower or a Subsidiary securing such Person's obligations in respect of bankers' acceptances or letters of credit entered into in the ordinary course of business issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods;

(w) Liens arising from, or from UCC financing statement filings regarding, operating leases or consignments entered into by the Borrower or its Subsidiaries in the ordinary course of business;

(x) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into in the ordinary course of business;

(y) any encumbrance or restriction, including any put and call arrangements, related to Capital Stock in any Joint Venture set forth in the Organizational Documents of such Joint Venture or any related joint venture, shareholders' or similar agreement;

(z) Liens on insurance policies and the proceeds thereof securing the financing of the premiums with respect thereto;

(aa) to the extent constituting Liens, licenses and sublicenses under any Permitted Product Transaction;

(bb) Liens securing obligations of non-Loan Parties permitted pursuant to clause (w) of the definition of Permitted Indebtedness so long as such Liens do not encumber any assets of the Loan Parties; and

(cc) other Liens incurred in the ordinary course of business of Borrower or any Subsidiary of Borrower with respect to obligations in aggregate amount outstanding not to exceed at any time [***].

Notwithstanding the foregoing, no Liens on any Product, Product Patent or Registrations shall be permitted (other than non-consensual Liens constituting “Permitted Liens” and Liens described in clauses (a), (r), and (u) above).

“Permitted Product Agreement” means:

(a) with respect to a Product (Non-Core), a Product Agreement that grants a license or sublicense of any rights under any Product Intellectual Property Rights, Non-Exclusive Product Intellectual Property Rights, or Registrations that allows the licensee to develop, manufacture, research, seek Registrations for, or Commercialize a Product (Non-Core) anywhere in the world; and

(b) with respect to a Product (Core), a Product Agreement that grants a license or sublicense of any rights under any Product Intellectual Property Rights, Non-Exclusive Product Intellectual Property Rights, or Registrations that allows the licensee to (i) develop, manufacture, research, seek Registrations for, or Commercialize a Product (Core) only outside of the United States and its territories or (ii) develop or research (but not Commercialize) a Product (Core) on behalf of Borrower or any of its Subsidiaries within the United States and its territories (provided, that Borrower or its applicable Subsidiary shall either (A) obtain ownership of any Product Intellectual Property Rights generated under such Product Agreement or (B) otherwise obtain the right to exploit the Product (Core) under such Product Agreement);

provided any such Product Agreement (x) does not provide for the legal transfer of title to any Product Patents, Registrations or Intellectual Property Rights relating to a Product (Core), (y) permits the disclosure of royalty and similar reports to the Administrative Agent and the Lenders in accordance with Section 5.1(e)(i) and (z) in the case of any Product Agreement with respect to a Product (Core) is not a Restricted License; provided further, that for the avoidance of doubt, if a Product Agreement grants a license or sublicense under any Product Intellectual Property Rights, Non-Exclusive Product Intellectual Property Rights, or Registrations that allows such Person to Commercialize a Product (Core) anywhere inside the United States or its territories, such Product Agreement shall not be a “Permitted Product Agreement”.

“Permitted Product Transaction” means the grant of a license or sublicense under any Product Patents or Registrations pursuant to a Permitted Product Agreement; provided that (i) the consideration received for any such transaction shall be in an amount at least equal to the fair market value thereof (as reasonably determined by the Borrower’s Board of Directors), and (ii) no Event of Default shall have occurred and be continuing at the time of such transaction or result therefrom.

“Permitted Refinancing Indebtedness” means any Indebtedness of Borrower or any of its Subsidiaries issued in exchange for, or the net proceeds of which are used to renew, refund, refinance, replace, defease or discharge other Indebtedness of Borrower or any of its Subsidiaries; provided that:

(a) the principal amount (or accreted value, if applicable) of such Permitted Refinancing Indebtedness does not exceed the principal amount (or accreted value, if applicable) of the Indebtedness renewed, refunded, refinanced, replaced, defeased or discharged (plus all accrued interest on the Indebtedness and the amount of all fees and expenses, including premiums, incurred in connection therewith);

(b) such Permitted Refinancing Indebtedness has a final maturity date later than the final maturity date of, and has a Weighted Average Life to Maturity equal to or greater than the Weighted Average Life to Maturity of, the Indebtedness being renewed, refunded, refinanced, replaced, defeased or discharged;

(c) if the Indebtedness being renewed, refunded, refinanced, replaced, defeased or discharged is subordinated in right of payment to the Obligations, such Permitted Refinancing Indebtedness is subordinated in right of payment to, the Obligations on terms at least as favorable to Administrative Agent and the Lenders as those contained in the documentation governing the Indebtedness being renewed, refunded, refinanced, replaced, defeased or discharged;

(d) such Indebtedness is incurred either by Borrower or by the Subsidiary who is the obligor on the Indebtedness being renewed, refunded, refinanced, replaced, defeased or discharged; and

(e) in the case of Permitted Convertible Indebtedness, such Indebtedness complies with the terms set forth in the proviso of the definition of Permitted Convertible Indebtedness.

“Person” means and includes natural persons, corporations, companies, limited partnerships, general partnerships, limited liability companies, limited liability partnerships, joint stock companies, Joint Ventures, associations, companies, trusts, banks, trust companies, land trusts, business trusts or other organizations, whether or not legal entities, and Governmental Authorities.

“Personal Information” means (i) any information that relates to, identifies or can be used to identify a natural person or (ii) any information defined as “personal data,” “personally identifiable information,” “personal information,” “protected health information,” “nonpublic personal information,” or similar term under applicable Data Protection Laws.

“Pledge and Security Agreement” means the Pledge and Security Agreement executed by Grantors in favor of Administrative Agent for the benefit of the Secured Parties.

“Prepayment Premium” has the meaning specified in the Fee Letter.

“Prime Rate” means the rate of interest quoted in *The Wall Street Journal*, Money Rates Section as the Prime Rate (currently defined as the base rate on corporate loans posted by at least 75% of the nation’s thirty (30) largest banks), as in effect from time to time. The Prime Rate is a reference rate and does not necessarily represent the lowest or best rate actually charged to any customer. The Administrative Agent or any other Lender may make commercial loans or other loans at rates of interest at, above or below the Prime Rate.

“Principal Office” means Administrative Agent’s “Principal Office” as set forth on Appendix B, or such other office as such Person may from time to time designate in writing to Borrower and each Lender.

“Privacy Policies” has the meaning specified in Section 4.36.

“Pro Rata Share” means, with respect to:

(a) (i) a Lender’s obligation to make the Initial Term Loan, the percentage obtained by dividing (A) such Lender’s Term Loan Commitment by (B) the Total Term Loan Commitment; and (ii) a Lender’s right to make an Incremental Term Loan, the percentage obtained by dividing (A) such Lender’s outstanding Term Loans by (B) the aggregate amount of all Lenders’ outstanding Term Loans;

(b) a Lender’s right to receive payments of interest, fees and principal with respect to a Term Loan, the percentage obtained by dividing (i) the aggregate unpaid principal amount of such Lender’s portion of the Term Loan, by (ii) the aggregate unpaid principal amount of the Term Loan; and

(c) all other matters, the percentage obtained by dividing (i) the unpaid principal amount of such Lender’s portion of the Term Loan, by (ii) the aggregate unpaid principal amount of the Term Loan.

“Product” means BRIUMVI and any other product/development candidate being developed or Commercialized by Borrower or the Loan Parties from time to time, including any acquired Product that is acquired or in-licensed pursuant to a Permitted Acquisition.

“Product (Core)” means BRIUMVI and any Competing Product with respect to BRIUMVI.

“Product (Core) Intellectual Property Rights” means Product Intellectual Property Rights and Non-Exclusive Product Intellectual Property Rights relating to any Product (Core).

“Product (Non-Core)” means any Product other than Product (Core).

“Product Agreement” means any agreement entered into between Borrower or any of its Subsidiaries with another Person that includes the granting of a license or sublicense of any rights under any Product Intellectual Property Rights, Non-Exclusive Product Intellectual Property Rights, or Registrations that allows such Person to develop, manufacture, research, seek Registrations for, or Commercialize a Product.

“Product Intellectual Property Rights” means (a) the Product Patents and (b) any and all Intellectual Property Rights owned by or exclusively licensed to, or purported to be owned by or exclusively licensed to, Borrower or its Affiliates relating to any Product.

“Product Patents” means the U.S. and foreign Patents owned or in-licensed by Borrower or any of its Subsidiaries, now or in the future, that are necessary or material to the research, development, manufacture, use, or Commercialization of one or more of the Products.

“Protective Advances” has the meaning specified in Section 9.11.

“Public Health Laws” means all Requirements of Law relating to the procurement, development, clinical and non-clinical evaluation, product approval or licensure, manufacture, production, analysis, wholesale, distribution, dispensing, importation, exportation, use, handling, quality, sale, labeling, promotion, clinical trial registration or post market requirements of any drug products (including, without limitation, any ingredient or component of the foregoing products) subject to regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) or Public Health Service Act (42 U.S.C. §262 et seq.), including without limitation the regulations promulgated by the FDA at Title 21 of the Code of Federal Regulations, and comparable foreign legislation issued by other comparable Governmental Authorities, including foreign Governmental Authorities, as well as applicable Requirements of Law relating to the licensure of entities that manufacture or distribute drug products.

“Purple Book Patents” means any Product Patents provided to a biosimilar applicant pursuant to 42 U.S.C. § 262, as such patent listing may be amended from time to time, together with all foreign counterpart patents.

“Qualified Capital Stock” means, with respect to any Person, all Capital Stock of such Person that are not Disqualified Capital Stock.

“Qualified Cash” means, as of any date of determination, the amount of unrestricted Cash and Cash Equivalents (other than restrictions created by the Collateral Documents) of the Loan Parties that is in Deposit Accounts or in Securities Accounts, or any combination thereof, which such Deposit Accounts or Securities Accounts are (after the post-closing period set forth in Section 5.13) subject to a Control Agreement.

“Real Estate Asset” means, at any time of determination, any Real Property owned by a Loan Party, but only to the extent such Real Property constitutes Collateral and is encumbered by a Mortgage pursuant to the terms of this Agreement.

“Real Property” means any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by Borrower or any of its Subsidiaries.

“Recipient” means (a) the Administrative Agent or (b) any Lender, as applicable.

“Register” has the meaning specified in Section 2.3(b).

“Registrations” means authorizations, approvals, licenses, permits, certificates, registrations, listings, certificates, or exemptions of or issued by any Governmental Authority (including marketing approvals, investigational new drug applications, product recertifications, manufacturing approvals and authorizations, pricing and reimbursement approvals, labeling approvals or their foreign equivalent) that are required for the research, development, manufacture, commercialization, distribution, marketing, storage, transportation, pricing, Governmental Authority reimbursement, use and sale of Products.

“Regulation D” means Regulation D of the Board of Governors of the Federal Reserve System, as in effect from time to time.

“Regulatory Action” means an administrative or regulatory enforcement action, proceeding or investigation, settlement agreement, corporate integrity agreement, deferred or non-prosecution agreement, warning letter, untitled letter, Form 483 or similar inspectional observations, civil investigative demand, subpoena, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, or consent decree, issued or required by the FDA, the U.S. Department of Health and Human Services or its departments thereunder, or under the Public Health Laws, or a comparable Governmental Authority in any other regulatory jurisdiction.

“Related Fund” means, with respect to any Lender that is an investment fund, any other investment fund that invests in commercial loans and that is managed or advised by the same investment advisor as such Lender or by an Affiliate of such investment advisor.

“Release” means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater.

“Relevant Governmental Body” means the Federal Reserve Board or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board or the Federal Reserve Bank of New York or any successor thereto.

“Remedial Action” means all actions taken to (a) correct or address any actual or threatened non-compliance with Environmental Law, (b) clean up, remove, remediate, contain, treat, monitor, assess, evaluate or in any other way address Hazardous Materials in the indoor or outdoor environment, (c) prevent or minimize a Release or threatened Release of Hazardous Materials so they do not migrate or endanger or threaten to endanger public health or welfare or the indoor or outdoor environment, (d) perform pre-remedial studies and investigations and post-remedial operation and maintenance activities; or (e) perform any other actions authorized or required by Environmental Law or Governmental Authority.

“Required Lenders” means, as of any date of determination, Lenders whose Pro Rata Share (calculated in accordance with clause (c) of the definition thereof) aggregate at least 50.1% as of such date; provided, that, Required Lenders shall include (x) each Blue Owl Affiliated Lender if, as of such date, Blue Owl and its Affiliates and Related Funds collectively hold at least [***]% of the outstanding principal amount of the Term Loans and (y) each HCR Affiliated Lender if, as of such date, HCR and its Affiliates and Related Funds holds at least [***]% of the outstanding principal amount of the Term Loans.

“Required Prepayment Date” has the meaning specified in Section 2.11(a).

“Requirements of Law” means, with respect to any Person, collectively, the common law and all federal, state, provincial, local, foreign, multinational or international laws, statutes, codes, treaties, standards, rules and regulations, guidelines, ordinances, orders, judgments, writs, injunctions, decrees (including administrative or judicial precedents or authorities) and the interpretation or administration thereof by, and other determinations, directives, requirements or requests of, any Governmental Authority, in each case, that are applicable to and binding upon such Person or any of its property or to which such Person or any of its property is subject.

“Resolution Authority” means an EEA Resolution Authority or, with respect to any UK Financial Institution, a UK Resolution Authority.

“Restricted Junior Payment” means (a) any dividend or other distribution, direct or indirect, on account of any shares of any class of Capital Stock of Borrower now or hereafter outstanding, except a dividend payable solely in shares of Capital Stock to the holders of that class, together with any payment or distribution pursuant to a “plan of division” under the Delaware Limited Liability Act or any comparable transaction under any similar law, (b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of any shares of any class of Capital Stock of Borrower or any of its Subsidiaries that is not a Loan Party now or hereafter outstanding, (c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Capital Stock of Borrower or any of its Subsidiaries that is not a Loan Party now or hereafter outstanding, (d) [reserved], and (e) any payment or prepayment of principal of, premium, if any, or interest on, or redemption, purchase, retirement, defeasance (including in substance or legal defeasance), sinking fund or similar payment with respect to, any Indebtedness that is contractually subordinated to the Obligations.

“Restricted License” means any Product Agreement (excluding any Product Agreement in the ordinary course of business granting only non-exclusive rights, and that does not materially interfere with, and is not material to, the conduct of the business of Borrower or any of its Subsidiaries in the ordinary course and that is otherwise permitted under this Agreement) that (a) cannot be collaterally assigned to secure the Obligations or otherwise contains provisions that restrict or penalize the granting of a security interest in or Lien on such Product Agreement or the related Product Intellectual Property Rights, (b) restricts the assignment of such Product Agreement upon the sale or other disposition of all or substantially all of the assets to which such Product Agreement relates (other than customary provisions requiring the assumption by the applicable purchaser of all obligations under such Product Agreement), or (c) does not permit the disclosure of information to be provided thereunder to Administrative Agent and the Lenders, any purchaser or prospective purchaser in a foreclosure or other Asset Sale of all or any portion of the Collateral (subject to customary confidentiality obligations); provided a Product Agreement shall not be a “Restricted Licenses” by virtue of clause (c) if Borrower or the applicable Subsidiary has used commercially reasonable efforts to permit, or other obtain permission for, such disclosure.

“Restricted Period” means [***].

“Royalty Monetization Transaction” means any monetization or financing transaction involving (a) the sale, transfer, option or collateralization of (i) any monetary payments (contingent or otherwise) payable to Borrower or its Subsidiaries by a counterparty under a Product Agreement, or (ii) any revenues generated through the commercial sale of the Product to third parties, in each case whether in whole or in part or (b) the provision of financing for the development, manufacture or Commercialization of any Product in exchange for the future payment of royalties, milestones and other amounts (whether or not contingent), including sales of royalty streams, royalty bonds and other royalty financings, synthetic royalty, development financing, and revenue interest transactions (including clinical trial funding arrangements), and hybrid monetization transactions.

“S&P” means Standard & Poor’s Ratings Group, a division of The McGraw Hill Corporation.

“Sanctioned Entity” means (a) a country or territory or a government of a country or territory, (b) an agency of the government of a country or territory, (c) an organization directly or indirectly controlled by the government of a country or territory, or (d) a Person resident in or determined to be resident in a country or territory, in each case of clauses (a) through (d) that is itself the target of Sanctions, including a target of any country or territory-based comprehensive sanctions or embargo program administered and enforced by OFAC (as of the date of this Agreement, Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, and the so-called Donetsk People’s Republic (DNR) and Luhansk People’s Republic (LNR) regions of Ukraine).

“Sanctioned Person” means, at any time (a) any Person named on the list of Specially Designated Nationals and Blocked Persons maintained by OFAC, OFAC’s consolidated Non-SDN list or any other Sanctions-related list maintained by any Governmental Authority, (b) a Person or legal entity that is itself the target of Sanctions, (c) any Person operating, organized or resident in a country or territory subject to an OFAC comprehensive sanctions or embargo program (as of the date of this Agreement, Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, and the so-called Donetsk People’s Republic (DNR) and Luhansk People’s Republic (LNR) regions of Ukraine), or (d) any Person directly or indirectly owned 50.0% or more or controlled (individually or in the aggregate) by or acting on behalf of any such Person or Persons described in clauses (a) through (c) above.

“Sanctions” means individually and collectively, respectively, any and all economic sanctions, trade sanctions, financial sanctions, sectoral sanctions, secondary sanctions, trade embargoes anti-terrorism laws and other sanctions laws, regulations or embargoes, including those imposed, administered or enforced from time to time by: (a) the United States of America, including those administered by OFAC, the U.S. Department of State, the U.S. Department of Commerce, or through any existing or future executive order, (b) the United Nations Security Council, (c) the European Union or any European Union member state, (d) His Majesty’s Treasury of the United Kingdom, or (e) any other Governmental Authority with jurisdiction over any Lender or any Loan Party or any of their respective Subsidiaries or Affiliates.

“Secured Parties” has the meaning assigned to that term in the Pledge and Security Agreement.

“Securities Account” means a securities account (as defined in the UCC).

“Securities Act” means the Securities Act of 1933.

“SOFR” means a rate equal to the secured overnight financing rate as administered by the SOFR Administrator.

“SOFR Administrator” means the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate).

“SOFR Loan” means a Loan bearing interest at a rate determined by reference to Term SOFR (other than pursuant to clause (c) of the definition of “Base Rate”).

“Solvency Certificate” means a Solvency Certificate substantially in the form of Exhibit E.

“Solvent” means, with respect to any Loan Party, that as of the date of determination, both (a)(i) the sum of such Loan Party’s debt (including contingent liabilities) does not exceed the present fair saleable value of such Loan Party’s present assets, (ii) such Loan Party’s capital is not unreasonably small in relation to its business as contemplated on the Closing Date, and (iii) such Loan Party has not incurred and does not intend to incur, or believe (nor should it reasonably believe) that it will incur, debts beyond its ability to pay such debts as they become due (whether at maturity or otherwise) and (b) such Person is “solvent” within the meaning given that term and similar terms under applicable laws relating to fraudulent transfers and conveyances. For purposes of this definition, the amount of any contingent liability at any time shall be computed as the amount that, in light of all of the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability (irrespective of whether such contingent liabilities meet the criteria for accrual under Statement of Financial Accounting Standard No. 5).

“Specified Jurisdiction” means, each of [***].

“Subsidiary” means, with respect to any Person, any corporation, company, partnership, limited liability company, association, joint venture or other business entity of which more than 50% of the total voting power of shares of stock, shares, or other ownership interests entitled (without regard to the occurrence of any contingency) to vote in the election of the Person or Persons (whether directors, managers, trustees or other Persons performing similar functions) having the power to direct or cause the direction of the management and policies thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person or a combination thereof; provided, in determining the percentage of ownership interests of any Person controlled by another Person, no ownership interest in the nature of a “qualifying share” of the former Person shall be deemed to be outstanding. When used herein, “Subsidiary” shall mean a Subsidiary of Borrower unless otherwise specified.

“Tax” means any present or future tax, levy, impost, duty, withholding (including backup withholding) assessment, fee or other charge imposed by any Governmental Authority, and any interest, penalties, additions to tax or other liabilities with respect thereto.

“Term Loan” means, collectively, the Initial Term Loan and each Incremental Term Loan (if any).

“Term Loan Commitment” means the commitment of a Lender to make or otherwise fund the Initial Term Loan and “Term Loan Commitments” means such commitments of all such Lenders in the aggregate. The amount of each Lender’s Term Loan Commitment, if any, is set forth on Appendix A. The aggregate amount of the Term Loan Commitments as of the Closing Date is \$250,000,000.

“Term Loan Maturity Date” means the earlier of (a) August [2], 2029 and (b) the date that the Term Loan shall become due and payable in full hereunder, whether by acceleration or otherwise.

“Term SOFR” means,

(a) for any calculation with respect to a SOFR Loan, the Term SOFR Reference Rate for a tenor comparable to the applicable Interest Period on the day (such day, the “Periodic Term SOFR Determination Day”) that is two (2) U.S. Government Securities Business Days prior to the first day of such Interest Period, as such rate is published by the Term SOFR Administrator; provided, however, that if as of 5:00 p.m. (New York City time) on any Periodic Term SOFR Determination Day the Term SOFR Reference Rate for the applicable tenor has not been published by the Term SOFR Administrator and a Benchmark Replacement Date with respect to the Term SOFR Reference Rate has not occurred, then Term SOFR will be the Term SOFR Reference Rate for such tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than three (3) U.S. Government Securities Business Days prior to such Periodic Term SOFR Determination Day, and

(b) for any calculation with respect to a Base Rate Loan on any day, the Term SOFR Reference Rate for a tenor of three months on the day (such day, the “Base Rate Term SOFR Determination Day”) that is two (2) U.S. Government Securities Business Days prior to such day, as such rate is published by the Term SOFR Administrator; provided, however, that if as of 5:00 p.m. (New York City time) on any Base Rate Term SOFR Determination Day the Term SOFR Reference Rate for the applicable tenor has not been published by the Term SOFR Administrator and a Benchmark Replacement Date with respect to the Term SOFR Reference Rate has not occurred, then Term SOFR will be the Term SOFR Reference Rate for such tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than three (3) U.S. Government Securities Business Days prior to such Base Rate Term SOFR Determination Day;

provided, further, that if Term SOFR determined as provided above (including pursuant to the proviso under clause (a) or clause (b) above) shall ever be less than the Floor, then Term SOFR shall be deemed to be the Floor.

“Term SOFR Administrator” means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of the Term SOFR Reference Rate selected by the Administrative Agent in its reasonable discretion).

“Term SOFR Reference Rate” means the forward-looking term rate based on SOFR.

“Test Date” has the meaning specified in the definition of Excluded Subsidiary.

“Title Company” has the meaning specified in Section 5.11.

“Title Policy” has the meaning specified in Section 5.11.

“Total Debt” means, as of any date of determination, the aggregate outstanding principal amount of third party Indebtedness of the Borrower and its Subsidiaries consisting of Indebtedness of the type described in clause (a), (b), (c) or (g) of the definition thereof.

“Total Net Leverage Ratio” means, as of any date of determination, the ratio of (x) the sum of (i) Total Debt as of such date *minus* (ii) the lesser of (a) Qualified Cash as of such date and (b) \$[***], to (y) Adjusted EBITDA for the most recently ended Measurement Period.

“Total Term Loan Commitment” means the sum of the amounts of the Lenders’ Term Loan Commitments.

“Trading Day” means a day on which exchanges in the United States are open for the buying and selling of securities.

“Transaction Costs” means the reasonable and documented fees, costs and expenses payable by the Borrower or any of its Subsidiaries on or before the Closing Date in connection with the transactions contemplated by the Loan Documents (including the Closing Date Refinancing).

“Type of Loan” means with respect to any Term Loan, a Base Rate Loan or a SOFR Loan.

“U.S.” or “United States” means the United States of America (including all possessions and territories thereof).

“U.S. Government Securities Business Day” means any day except for (a) a Saturday, (b) a Sunday or (c) a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

“U.S. Tax Compliance Certificate” has the meaning specified in Section 2.15(d)(i)(B)(3).

“UCC” means the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

“UK Financial Institution” means any BRRD Undertaking (as such term is defined under the PRA Rulebook (as amended from time to time) promulgated by the United Kingdom Prudential Regulation Authority) or any person falling within IFPRU 11.6 of the FCA Handbook (as amended from time to time) promulgated by the United Kingdom Financial Conduct Authority that includes certain credit institutions and investment firms, and certain affiliates of such credit institutions or investment firms.

“UK Resolution Authority” means the Bank of England or any other public administrative authority having responsibility for the resolution of any UK Financial Institution.

“Unadjusted Benchmark Replacement” means the applicable Benchmark Replacement excluding the related Benchmark Replacement Adjustment.

“US Net Sales” means, with respect to each Measurement Period, [***].

“US Net Sales Calculation” means the most recent certified calculation of US Net Sales delivered to the Administrative Agent in the Compliance Certificate accompanying the financial statements delivered pursuant to Section 5.1(b) or (c), as applicable, and Section 5.1(d).

“Waivable Mandatory Prepayment” has the meaning specified in Section 2.11(b).

“Weighted Average Life to Maturity” means, when applied to any Indebtedness at any date, the number of years obtained by dividing:

(a) the sum of the products obtained by multiplying (i) the amount of each then remaining installment, sinking fund, serial maturity or other required payments of principal, including payment at final maturity, in respect of the Indebtedness, by (ii) the number of years (calculated to the nearest one-twelfth) that will elapse between such date and the making of such payment; by

(b) the then outstanding principal amount of such Indebtedness.

“Withdrawal Event” means (a) any voluntary withdrawal or removal of one or both of (i) BRIUMVI or (ii) any Competing Product (excluding, in each case (i) or (ii), a recall, removal, market withdrawal, or correction of BRIUMVI or a Competing Product that involves a minor violation that would not be subject to legal action by the FDA (or international equivalent thereof) or that involves no violation of FDA Laws), (b) the loss of marketing authorization for any Product (Core), or (c) the Borrower or any of its Subsidiaries receives a notification from a Governmental Authority that it intends to withdraw marketing approval of any Product (Core) or such notification is published in the Federal Register or other equivalent information source (each, a “Regulatory Withdrawal Notice”) [***], in each case of (a), (b) and (c), with respect to a Material Jurisdiction. [***].

“Write-Down and Conversion Powers” means, (a) with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule, and (b) with respect to the United Kingdom, any powers of the applicable Resolution Authority under the Bail-In Legislation to cancel, reduce, modify or change the form of a liability of any UK Financial Institution or any contract or instrument under which that liability arises, to convert all or part of that liability into shares, securities or obligations of that person or any other person, to provide that any such contract or instrument is to have effect as if a right had been exercised under it or to suspend any obligation in respect of that liability or any of the powers under that Bail-In Legislation that are related to or ancillary to any of those powers.

Section 1.2 Accounting and Other Terms.

(a) Except as otherwise expressly provided herein, all accounting terms not otherwise defined herein shall have the meanings assigned to them in conformity with GAAP. Financial statements and other information required to be delivered by Borrower to Lenders pursuant to Sections 5.1(b) and 5.1(c) shall be prepared in accordance with GAAP as in effect at the time of such preparation. Subject to the foregoing, calculations in connection with the definitions, covenants and other provisions hereof shall utilize accounting principles and policies in conformity with those used to prepare the Historical Financial Statements. Notwithstanding the foregoing, for purposes of determining compliance with any covenant (including the computation of any financial covenant) contained herein, (i) Indebtedness of Borrower and its Subsidiaries shall be deemed to be carried at 100% of the outstanding principal amount thereof, and the effects of FASB ASC 825 and FASB ASC 470 20 on financial liabilities shall be disregarded, (ii) with respect to the accounting for leases as either operating leases or capital leases and the impact of such accounting in accordance with FASB ASC 840 on the definitions and covenants herein, GAAP as in effect on December 1, 2018 shall be applied and (iii) with respect to revenue recognition and the impact of such accounting in accordance with FASB ASC 606 on the definitions and covenants herein, GAAP as in effect on December 31, 2017 shall be applied. Notwithstanding anything to the contrary above or in the definition of “Capital Lease”, all obligations of any Person that are or would have been treated as operating leases for purposes of GAAP prior to the effectiveness of ASC 842 shall continue to be accounted for as operating leases for all purposes hereunder or under any other Loan Documents (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with ASC 842 (on a prospective or retroactive basis or otherwise) to be treated as Capital Leases.

(b) All terms used in this Agreement that are defined in Article 8 or Article 9 of the UCC as in effect from time to time in the State of New York and that are not otherwise defined herein shall have the same meanings herein as set forth therein, provided that terms used herein that are defined in the UCC as in effect in the State of New York on the date hereof shall continue to have the same meaning notwithstanding any replacement or amendment of such statute except as Administrative Agent may otherwise determine.

(c) For purposes of determining compliance with any incurrence or expenditure tests set forth in this Agreement, any amounts so incurred or expended (to the extent incurred or expended in a currency other than Dollars (\$)) shall be converted into Dollars on the basis of the exchange rates (as shown on the Bloomberg currency page for such currency or, if the same does not provide such exchange rate, by reference to such other recognized and publicly available service for displaying exchange rates as may be reasonably selected by Administrative Agent or, in the event no such service is available, on such other basis as is reasonably satisfactory to Administrative Agent) as in effect on the date of such incurrence or expenditure under any provision of any such Section that has an aggregate Dollar limitation provided for therein (and to the extent the respective incurrence or expenditure test regulates the aggregate amount outstanding at any time and it is expressed in terms of Dollars, all outstanding amounts originally incurred or spent in currencies other than Dollars shall be converted into Dollars on the basis of the exchange rates (as shown on the Bloomberg currency page for such currency or, if the same does not provide such exchange rate, by reference to such other recognized and publicly available service for displaying exchange rates as may be reasonably selected by Administrative Agent or, in the event no such service is available, on such other basis as is reasonably satisfactory to Administrative Agent) as in effect on the date of any new incurrence or expenditures made under any provision of any such Section that regulates the Dollar amount outstanding at any time).

Section 1.3 Interpretation, Etc.

Any of the terms defined herein may, unless the context otherwise requires, be used in the singular or the plural, depending on the reference. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms. The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "or" is used in the inclusive sense (and/or). References herein to any Section, Appendix, Schedule or Exhibit shall be to a Section, an Appendix, a Schedule or an Exhibit, as the case may be, hereof unless otherwise specifically provided. The use herein of the word "include" or "including," when following any general statement, term or matter, shall not be construed to limit such statement, term or matter to the specific items or matters set forth immediately following such word or to similar items or matters, whether or not no limiting language (such as "without limitation" or "but not limited to" or words of similar import) is used with reference thereto, but rather shall be deemed to refer to all other items or matters that fall within the broadest possible scope of such general statement, term or matter. The words "asset" and "property" shall be construed to have the same meaning and effect and to refer to any right or interest in or to assets and properties of any kind whatsoever, whether real, personal or mixed and whether tangible or intangible. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Any reference herein or in any other Loan Document to the satisfaction, repayment, or payment in full of the Obligations or Guaranteed Obligations shall mean (a) the payment or repayment in full in immediately available funds of (i) the principal amount of, and interest accrued and unpaid with respect to, all outstanding Loans, together with the payment of any premium applicable to the repayment of the Loans, including any Applicable Premium and any Prepayment Premium, (ii) all costs, expenses, or indemnities payable pursuant to Section 10.2 or Section 10.3 of this Agreement that have accrued and are unpaid regardless of whether demand has been made therefor, and (iii) all fees, charges (including loan fees, service fees, professional fees, and expense reimbursement) and other Obligations that have accrued hereunder or under any other Loan Document and are unpaid, and (iv) the termination of all of the Term Loan Commitments. Notwithstanding anything in this Agreement to the contrary, (A) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (B) all requests, rules, guidelines or directives concerning capital adequacy promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities shall, in each case, be deemed to be enacted, adopted, issued, phased in or effective after the date of this Agreement regardless of the date enacted, adopted, issued, phased in or effective. Unless the context requires otherwise (a) any definition of or reference to any Loan Document, agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth in any Loan Document), (b) any reference to any law or regulation shall (i) include all statutory and regulatory provisions consolidating, amending, replacing or interpreting or supplementing such law or regulation, and (ii) unless otherwise specified, refer to such law or regulation as amended, modified or supplemented from time to time, and (c) any reference herein to any Person shall be construed to include such Person's successors and permitted assigns. This Section 1.3 shall apply, *mutatis mutandis*, to all Loan Documents.

Section 1.4 Time References. Unless otherwise indicated herein, all references to time of day refer to Eastern Standard Time or Eastern daylight saving time, as in effect in New York City on such day. For purposes of the computation of a period of time from a specified date to a later specified date, the word “from” means “from and including” and the words “to” and “until” each means “to but excluding”; provided, however, that with respect to a computation of fees or interest payable to Administrative Agent or any Lender, such period shall in any event consist of at least one full day.

Section 1.5 Certain Matters of Construction. References in this Agreement to “determination” by Administrative Agent include good faith estimates by Administrative Agent (in the case of quantitative determinations) and good faith beliefs by Administrative Agent (in the case of qualitative determinations). A Default or Event of Default shall be deemed to exist at all times during the period commencing on the date that such Default or Event of Default occurs to the date on which such Default or Event of Default is cured or waived in writing pursuant to this Agreement or, in the case of a Default, is cured within any period of cure expressly provided for in this Agreement; and an Event of Default shall “continue” or be “continuing” until such Event of Default has been cured or waived in writing by the Required Lenders. Any Lien referred to in this Agreement or any other Loan Document as having been created in favor of Administrative Agent, any agreement entered into by Administrative Agent pursuant to this Agreement or any other Loan Document, any payment made by or to or funds received by Administrative Agent pursuant to or as contemplated by this Agreement or any other Loan Document, or any act taken or omitted to be taken by Administrative Agent, shall, unless otherwise expressly provided, be created, entered into, made or received, or taken or omitted, for the benefit or account of Administrative Agent and the Lenders. All covenants hereunder shall be given independent effect so that if a particular action or condition is not permitted by any of such covenants, the fact that it would be permitted by an exception to, or otherwise within the limitations of, another covenant shall not avoid the occurrence of a default if such action is taken or condition exists. In addition, all representations and warranties hereunder shall be given independent effect so that if a particular representation or warranty proves to be incorrect or is breached, the fact that another representation or warranty concerning the same or similar subject matter is correct or is not breached will not affect the incorrectness of a breach of a representation or warranty hereunder. If at any time any action or transaction meets the criteria of one or more than one of the categories of exceptions, thresholds or baskets set forth in any Section of Article VI or any definition used therein, the Borrower or its Subsidiaries may divide, classify or designate such action or transaction (or any portion thereof), and later (on one or more occasions) may re-divide, re-classify or re-designate such action or transaction (or any portion thereof), as consummated in reliance on one or more of such exceptions, thresholds and baskets within such Section of Article VI as the Borrower or any of its Subsidiaries may determine in their sole discretion from time to time. All references to “in the ordinary course of business” of the Borrower or any Subsidiary thereof means (i) in the ordinary course of business of, or in furtherance of an objective that is in the ordinary course of business of the Borrower or such Subsidiary, as applicable, (ii) customary and usual in the industry or industries of the Borrower and its Subsidiaries in the United States or any other jurisdiction in which the Borrower or any Subsidiary does business, as applicable, and (iii) generally consistent with the past or current practice of the Borrower or such Subsidiary, as applicable, or any similarly situated businesses of the United States or any other jurisdiction in which the Borrower or any Subsidiary does business, as applicable.

Section 1.6 Rates. Administrative Agent does not warrant or accept any responsibility for, and shall not have any liability with respect to, (a) the continuation of, administration of, submission of, calculation of or any other matter related to the Term SOFR Reference Rate, Term SOFR or any other Benchmark, any component definition thereof or rates referred to in the definition thereof, or with respect to any alternative, successor or replacement rate thereto (including any then-current Benchmark or any Benchmark Replacement), including whether the composition or characteristics of any such alternative, successor or replacement rate (including any Benchmark Replacement), as it may or may not be adjusted pursuant to Section 2.20, will be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as, the Term SOFR Reference Rate, Term SOFR or any other Benchmark, prior to its discontinuance or unavailability, or (b) the effect, implementation or composition of any Conforming Changes. Administrative Agent and its affiliates or other related entities may engage in transactions that affect the calculation of the Term SOFR Reference Rate, Term SOFR, any alternative, successor or replacement rate (including any Benchmark Replacement) or any relevant adjustments thereto and such transactions may be adverse to Borrower. Administrative Agent may select information sources or services in its reasonable discretion to ascertain the Term SOFR Reference Rate or Term SOFR, or any other Benchmark, any component definition thereof or rates referred to in the definition thereof, in each case pursuant to the terms of this Agreement, and shall have no liability to Borrower, any Lender or any other person or entity for damages of any kind, including direct or indirect, special, punitive, incidental or consequential damages, costs, losses or expenses (whether in tort, contract or otherwise and whether at law or in equity), for any error or calculation of any such rate (or component thereof) provided by any such information source or service.

Section 1.7 Financial Metrics. For purposes of determining any financial metric, including, without limitation, Consolidated Total Assets of the Borrower and its Subsidiaries, in connection with any test, requirement, condition or calculation using such metric required hereunder to determine whether any action taken or to be taken by the Borrower is permitted hereunder, the Borrower shall use such number as of the last date for which the Borrower has, or is required to have, delivered financial reporting under Section 5.1 hereof (giving pro forma effect to the proposed action).

Section 1.8 Calculation of Baskets. If any of the baskets set forth in Article VI of this Agreement are exceeded solely as a result of currency fluctuations or fluctuations in the Total Net Leverage Ratio or in Consolidated Total Assets for the most recently completed Fiscal Quarter after the last time such baskets were calculated for any purpose under this Agreement, such baskets will not be deemed to have been exceeded solely as a result of such fluctuations.

ARTICLE II

LOANS

Section 2.1 Term Loans.

(a) Initial Term Loans; Incremental Term Loans. Subject to the terms and conditions hereof:

(i) each Lender severally agrees to make, on the Initial Funding Date, an Initial Term Loan to Borrower in an amount equal to such Lender's Term Loan Commitment; and

(ii) at the option of Borrower, and subject to the approval of Lenders in their sole discretion, each Lender may, severally and not jointly, make Incremental Term Loans to Borrower in an aggregate amount not to exceed \$100,000,000.00.

Borrower may make only one borrowing under the Term Loan Commitment, which shall be on the Initial Funding Date. Any amount borrowed under this Section 2.1(a) and subsequently repaid or prepaid may not be reborrowed. Subject to Section 2.9, all amounts owed hereunder with respect to the Term Loan shall be paid in full no later than the Term Loan Maturity Date. Each Lender's Term Loan Commitment shall terminate immediately and without further action on the Credit Date on which such Lender funds Initial Term Loans after giving effect to the funding of such Term Loans on such Credit Date.

(b) Borrowing Mechanics for Term Loans.

(i) Borrower shall deliver to Administrative Agent a fully executed Funding Notice no later than three Business Days prior to the Initial Funding Date (or such shorter period permitted by Administrative Agent), with respect to Term Loans made on the Initial Funding Date. Except as otherwise provided herein, a Funding Notice for a Term Loan that is a SOFR Loan shall be irrevocable on and after the related Interest Rate Determination Date, and Borrower shall be bound to make a borrowing in accordance therewith. Promptly upon receipt by Administrative Agent of any such Funding Notice, Administrative Agent shall notify each Lender of the proposed borrowing. Administrative Agent and Lenders (A) may act without liability upon the basis of written or facsimile notice believed by Administrative Agent in good faith to be from Borrower (or from any Authorized Officer thereof designated in writing purportedly from Borrower to Administrative Agent), (B) shall be entitled to rely conclusively on any Authorized Officer's authority to request a Term Loan on behalf of Borrower until Administrative Agent receives written notice to the contrary, and (C) shall have no duty to verify the authenticity of the signature appearing on any written Funding Notice.

(ii) Each Lender shall make its applicable Term Loan available to Administrative Agent not later than 12:00 p.m. on the applicable Credit Date, by wire transfer of same day funds in Dollars, at Administrative Agent's Principal Office. Upon satisfaction or waiver of the conditions precedent specified herein, Administrative Agent shall make the proceeds of the applicable Term Loans available to Borrower on the applicable Credit Date by causing an amount of same day funds in Dollars equal to the proceeds of all such Loans received by Administrative Agent from Lenders to be credited to the account of Borrower at Administrative Agent's Principal Office or to such other account as may be designated in writing to Administrative Agent by Borrower.

(iii) With respect to any Funding Notice requesting Incremental Term Loans, (a) the Administrative Agent shall promptly forward such Funding Notice to each Lender and (b) each Lender shall, within fifteen (15) U.S. Government Securities Business Days of receipt of such Funding Notice, elect or decline to commit, on the applicable Credit Date, to provide its Pro Rata Share of such Term Loans. During such fifteen (15) U.S. Government Securities Business Days period, Borrower shall provide to Administrative Agent, for distribution to the Lenders, such information as reasonably requested by Lenders, including, without limitation any information related to the use of funds of such Incremental Term Loans.

(c) Pro Rata Shares; Availability of Funds.

(i) Pro Rata Shares. All Loans (other than the Incremental Term Loans) shall be made by Lenders simultaneously and proportionately to their respective Pro Rata Shares, it being understood that no Lender shall be responsible for any default by any other Lender in such other Lender's obligation to make a Loan requested hereunder nor shall any Term Loan Commitment of any Lender be increased or decreased as a result of a default by any other Lender in such other Lender's obligation to make a Loan requested hereunder or purchase a participation required hereby.

(ii) Availability of Funds. Unless Administrative Agent shall have been notified by any Lender prior to the applicable Credit Date that such Lender does not intend to make available to Administrative Agent the amount of such Lender's Loan requested on such Credit Date, Administrative Agent may assume that such Lender has made such amount available to Administrative Agent on such Credit Date and Administrative Agent may, in its sole discretion, but shall not be obligated to, make available to Borrower a corresponding amount on such Credit Date. If such corresponding amount is not in fact made available to Administrative Agent by such Lender, Administrative Agent shall be entitled to recover such corresponding amount on demand from such Lender together with interest thereon, for each day from such Credit Date until the date such amount is paid to Administrative Agent, at the customary rate set by Administrative Agent for the correction of errors among banks for three Business Days and thereafter at the Base Rate. If such Lender does not pay such corresponding amount forthwith upon Administrative Agent's demand therefor, Administrative Agent shall promptly notify Borrower and Borrower shall immediately pay such corresponding amount to Administrative Agent together with interest thereon, for each day from such Credit Date until the date such amount is paid to Administrative Agent, at the rate payable hereunder for Base Rate Loans. Nothing in this Section 2.1(c)(ii) shall be deemed to relieve any Lender from its obligation to fulfill its Term Loan Commitments hereunder or to prejudice any rights that Borrower may have against any Lender as a result of any default by such Lender hereunder.

Section 2.2 Use of Proceeds. The proceeds of the Initial Term Loans shall be applied by Borrower (a) to finance the Closing Date Refinancing and to pay the Transaction Costs and (b) for working capital and general corporate purposes of the Borrower and its Subsidiaries. No portion of the proceeds of the Term Loan shall be used in any manner that causes or might cause such Credit Extension or the application of such proceeds to violate Regulation T, Regulation U or Regulation X of the Board of Governors of the Federal Reserve System or any other regulation thereof or to violate the Exchange Act.

Section 2.3 Evidence of Debt; Register; Lenders' Books and Records; Notes.

(a) Lenders' Evidence of Debt. Each Lender shall maintain on its internal records an account or accounts evidencing the Obligations of Borrower to such Lender, including the amounts of the Term Loans made by it and each repayment and prepayment in respect thereof. Any such recordation shall be conclusive and binding on Borrower, absent manifest error; provided, that the failure to make any such recordation, or any error in such recordation, shall not affect Borrower's Obligations in respect of any Term Loans; and provided further, in the event of any inconsistency between the Register and any Lender's records, the recordations in the Register shall govern.

(b) Register. Administrative Agent shall maintain at its Principal Office a register for the recordation of the names and addresses of Lenders and the commitments of and principal amount of the Term Loans (and stated interest therein) owing to each Lender from time to time (the "Register"). The Register shall be available for inspection by Borrower at any reasonable time and from time to time upon reasonable prior notice. The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement, notwithstanding any notice to the contrary; provided, failure to make any such recordation, or any error in such recordation, shall not affect Borrower's Obligations to repay any Term Loan in accordance with the terms of this Agreement. Borrower hereby designates the entity serving as Administrative Agent to serve as Borrower's non-fiduciary agent solely for purposes of maintaining the Register as provided in this Section 2.3. The parties intend that any interest in or with respect to the Loans under this Agreement be treated as being issued and maintained in "registered form" within the meaning of Sections 163(f), 871(h)(2), and 881(c)(2) of the Code and any regulations thereunder (and any successor provisions), including without limitation under United States Treasury Regulations Section 5f.103-1(c) and Proposed Regulations Section 1.163-5 (and any successor provisions).

(c) Notes. If so requested by any Lender by written notice to Borrower (with a copy to Administrative Agent) at least two Business Days prior to the Closing Date, or at any time thereafter, Borrower shall execute and deliver to such Lender (or, if applicable and if so specified in such notice, to any Person who is an assignee of such Lender pursuant to Section 10.6) on the Closing Date (or, if such notice is delivered after the Closing Date, promptly after Borrower's receipt of such notice) a Note or Notes.

Section 2.4 Interest.

(a) Except as otherwise set forth herein, each Loan shall bear interest on the unpaid principal amount thereof from the date made through repayment (whether by acceleration or otherwise) thereof as follows: (i) if a Base Rate Loan, at the Base Rate plus the Applicable Margin; or (ii) if a SOFR Loan, at Term SOFR plus the Applicable Margin.

(b) The basis for determining the rate of interest with respect to any Loan, and the Interest Period with respect to any SOFR Loan, shall be selected by Borrower and notified to Administrative Agent and Lenders pursuant to the applicable Funding Notice or Conversion/Continuation Notice, as the case may be. If on any day a Loan is outstanding with respect to which a Funding Notice or Conversion/Continuation Notice has not been delivered to Administrative Agent in accordance with the terms hereof specifying the applicable basis for determining the rate of interest, then for that day such Loan shall be a Base Rate Loan.

(c) In connection with SOFR Loans there shall be no more than five (5) Interest Periods outstanding at any time. In the event Borrower fails to specify between a Base Rate Loan or a SOFR Loan in the applicable Funding Notice or Conversion/Continuation Notice, such Loan (if outstanding as a SOFR Loan) will automatically continue as a SOFR Loan on the last day of the then current Interest Period for such Loan (or if outstanding as a Base Rate Loan will remain as, or (if not then outstanding) will be made as, a Base Rate Loan). At any time that an Event of Default has occurred and is continuing, Borrower no longer shall have the option to request that any portion of the Loans be a SOFR Loan and such SOFR Loans shall automatically convert to Base Rate Loans on the last day of the then current Interest Period. As soon as practicable after 1:00 p.m. (New York City time) on each Interest Rate Determination Date, Administrative Agent shall determine (which determination shall, absent manifest error, be final, conclusive and binding upon all parties) the interest rate that shall apply to the SOFR Loans for which an interest rate is then being determined for the applicable Interest Period and shall promptly give notice thereof (in writing) to Borrower and each Lender.

(d) Interest payable hereunder shall be computed on the basis of a 360 day year, in each case for the actual number of days elapsed in the period during which it accrues. In computing interest on any Loan, the date of the making of such Loan or the first day of an Interest Period applicable to such Loan or, with respect to a Base Rate Loan being converted from a SOFR Loan, the date of conversion of such SOFR Loan to such Base Rate Loan, as the case may be, shall be included, and the date of payment of such Loan or the expiration date of an Interest Period applicable to such Loan or, with respect to a Base Rate Loan being converted to a SOFR Loan, the date of conversion of such Base Rate Loan to such SOFR Loan, as the case may be, shall be excluded; provided, if a Loan is repaid on the same day on which it is made, one day's interest shall be paid on that Loan.

(e) Except as otherwise set forth herein, interest on each Term Loan shall be payable in cash and in arrears (i) on each Interest Payment Date and (ii) upon any prepayment of that Term Loan, whether voluntary or mandatory, to the extent accrued on the amount being prepaid.

(f) In connection with the use or administration of Term SOFR, Administrative Agent, in consultation with the Borrower, will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document. Administrative Agent will promptly notify Borrower and the Lenders of the effectiveness of any Conforming Changes in connection with the use or administration of Term SOFR.

Section 2.5 Conversion/Continuation.

(a) Subject to Section 2.17 and so long as no Event of Default shall have occurred and then be continuing, Borrower shall have the option:

(i) to convert at any time all or any part of any Term Loan equal to \$5,000,000 and integral multiples of \$5,000,000 in excess of that amount from one Type of Loan to another Type of Loan; provided, a SOFR Loan may only be converted on the expiration of the Interest Period applicable to such SOFR Loan unless Borrower shall pay all amounts due under Section 2.17 in connection with any such conversion; or

(ii) upon the expiration of any Interest Period applicable to any SOFR Loan, to continue all or any portion of such Loan equal to \$5,000,000 and integral multiples of \$5,000,000 in excess of that amount as a SOFR Loan.

(b) Borrower shall deliver a Conversion/Continuation Notice to Administrative Agent no later than 1:00 p.m. (New York City time) at least one (1) Business Day in advance of the proposed conversion date (in the case of a conversion to a Base Rate Loan) and at least three (3) Business Days in advance of the proposed conversion/continuation date (in the case of a conversion to, or a continuation of, a SOFR Loan). Except as otherwise provided herein, a Conversion/Continuation Notice for conversion to, or continuation of, any SOFR Loans shall be irrevocable on and after the related Interest Rate Determination Date, and Borrower shall be bound to effect a conversion or continuation in accordance therewith.

Section 2.6 Default Interest. Upon the occurrence and during the continuance of an Event of Default under Sections 8.1(a), (f) or (g), and after written notice from the Administrative Agent acting at the direction of the Required Lenders, after the occurrence and during the continuance of any other Event of Default, the principal amount of all Term Loans outstanding and, to the extent permitted by applicable law, any interest payments on the Term Loans or any fees or other amounts owed hereunder (including any Applicable Premium and Prepayment Premium, if applicable), shall thereafter bear interest (including post petition interest in any proceeding under the Bankruptcy Code or other applicable bankruptcy laws) payable on demand at a rate that is [***]% per annum in excess of the interest rate otherwise payable hereunder with respect to the Term Loans (the "Default Rate"). All interest payable at the Default Rate shall be payable in cash on demand. Payment or acceptance of the Default Rate of interest provided for in this Section 2.6 is not a permitted alternative to timely payment and shall not constitute a waiver of any Default or Event of Default or otherwise prejudice or limit any rights or remedies of Administrative Agent or any Lender.

Section 2.7 Fees.

(a) Borrower agrees to pay to Administrative Agent all fees payable by it in the Fee Letters in the amounts and at the times specified therein.

(b) All fees referred to in Section 2.7(a) shall be calculated on the basis of a 360 day year and the actual number of days elapsed.

Section 2.8 Repayment of Term Loans. The principal amounts of the Term Loans shall be repaid in quarterly installments (each, an "Installment") in the amounts set forth opposite each installment payment date in the table below:

Installment Payment Date	Term Loan Installments
***]	***]
***]	***]
***]	***]
***]	***]

Notwithstanding the foregoing, (x) [***], (y) the outstanding unpaid principal balance, together with all other amounts owed hereunder with respect thereto, shall, in any event, be paid in full in cash no later than the Term Loan Maturity Date; and (z) any Incremental Term Loans shall be repaid in accordance with the amortization schedule for such Incremental Term Loans in the Incremental Amendment applicable thereto.

Section 2.9 Voluntary Prepayments.

(a) Subject to the terms of the Fee Letter, Borrower may prepay at any time the Term Loan on any Business Day in whole or in part (together with any amounts due pursuant to Section 2.19), in an aggregate minimum amount of \$10,000,000 and integral multiples of \$5,000,000 in excess of that amount.

(b) All such prepayments shall be made upon not less than three (3) Business Day's prior written notice, in each case given to Administrative Agent by 1:00 p.m. on the date required (and Administrative Agent will promptly transmit such or original notice by facsimile or email to each Lender). Upon the giving of any such notice, the principal amount of the Term Loans specified in such notice shall become due and payable on the prepayment date specified therein; provided that Borrower may rescind any notice if (i) such prepayment would have resulted from a refinancing of the Term Loans or other contingent transaction and such refinancing or transaction shall not be consummated or shall otherwise be delayed, and (ii) such prior written notice states that such prepayment is conditioned upon the closing on the proposed date of prepayment of a refinancing of the Term Loans or other contingent transaction. Any such voluntary prepayment shall be applied as specified in Section 2.11(a), with respect to the Term Loans.

Section 2.10 Mandatory Prepayment.

(a) Asset Sales.

(i) No later than the [***] following the date of receipt by any Loan Party of any Net Proceeds from Asset Sales (other than any Asset Sale described in clauses (i) (solely with respect to an Asset Sale of Product (Core) pursuant to an agreement that satisfies the conditions of clause (b) of the definition of Permitted Product Agreement), (iv), (v), (vi), (vii), (viii), (ix), (x) or (xi) of Section 6.9(b)) in excess of (x) \$[***] in the aggregate with respect to Asset Sales of Product and (y) \$[***] in the aggregate with respect to any other Asset Sales (including, for the avoidance of doubt, any priority review voucher); provided, such prepayment shall not be required so long as (i) no Default or Event of Default shall have occurred and be continuing, (ii) Borrower has delivered Administrative Agent written notice of Borrower's intention to reinvest such monies in long-term or capital assets used or useful in the business of the Loan Parties, (iii) the Net Proceeds are held in a Deposit Account in which Administrative Agent has a perfected first-priority security interest, and (iv) the Loan Parties complete such reinvestment or purchase within [***] days after the initial receipt of such monies; provided, that if any such Net Proceeds are no longer intended to be or cannot be so reinvested or applied during the applicable [***] day period, and subject to Section 2.11(b), an amount equal to any such Net Proceeds shall, within [***] after Borrower reasonably determines that such Net Proceeds are no longer intended to be or cannot be so reinvested or applied, be applied to the prepayment of the Term Loans as set forth in Section 2.11(a).

(ii) Nothing contained in this Section 2.10(a) shall permit Borrower or any of its Subsidiaries to sell or otherwise dispose of any assets other than in accordance with Section 6.9.

(b) Insurance/Condemnation Proceeds. No later than the [***] following the date of receipt by any Loan Party, or Administrative Agent as loss payee, of any Net Proceeds from insurance or any condemnation, taking or other casualty in excess of \$[***], Borrower shall, subject to Section 2.12(b), prepay the Term Loan as set forth in Section 2.11(a) in an aggregate amount equal to such Net Proceeds in excess of \$[***]; provided, such prepayment shall not be required so long as (i) no Default or Event of Default shall have occurred and be continuing, (ii) Borrower has delivered Administrative Agent prior written notice of Borrower's intention to [***] reinvest such monies in long-term or capital assets used or useful in the business of the Loan Parties, (iii) the Net Proceeds are held in a Deposit Account in which Administrative Agent has a perfected first-priority security interest, and (iv) the Loan Parties complete such reinvestment or purchase within [***] days after the initial receipt of such monies; provided, that if any such Net Proceeds are no longer intended to be or cannot be so reinvested or applied during the applicable [***] day period, and subject to Section 2.11(b), an amount equal to any such Net Proceeds shall, within [***] after Borrower reasonably determines that such Net Proceeds are no longer intended to be or cannot be so reinvested or applied, be applied to the prepayment of the Term Loans as set forth in Section 2.11(a).

(c) Issuance of Debt. On the date of receipt by Borrower or any of its Subsidiaries of any Cash proceeds from the incurrence of any Indebtedness of Borrower or any of its Subsidiaries (other than with respect to any Indebtedness permitted to be incurred pursuant to Section 6.1), Borrower shall prepay the Loans in an aggregate amount equal to 100% of such proceeds, net of underwriting discounts and commissions and other reasonable costs and expenses associated therewith, in each case, paid to non-Affiliates, including reasonable legal fees and expenses.

(d) Prepayment Certificate. Concurrently with any prepayment of the Term Loan pursuant to Section 2.10(a) through Section 2.10(c), Borrower shall deliver to Administrative Agent a certificate of an Authorized Officer demonstrating the calculation of the amount of the applicable net proceeds and compensation owing to Lenders pursuant to the Fee Letter, if any, as the case may be. In the event that Borrower shall subsequently determine that the actual amount received exceeded the amount set forth in such certificate, Borrower shall promptly make an additional prepayment of the Loans, and Borrower shall concurrently therewith deliver to Administrative Agent a certificate of an Authorized Officer demonstrating the derivation of such excess.

Section 2.11 Application of Prepayments.

(a) Application of Prepayments of Term Loans. (i) Any prepayment of the Term Loan pursuant to Section 2.9 and (ii) except in connection with any Waivable Mandatory Prepayment provided for in Section 2.11(b), so long as no Application Event has occurred and is continuing, any mandatory prepayment of any Loan pursuant to Section 2.10, in each case, shall be applied as follows:

first, to prepay accrued and unpaid interest on the Term Loan;

second, to pay any Prepayment Premium and any Applicable Premium payable thereon; and

third, to prepay the principal of the (i) Initial Term Loan, subject to Section 2.8, ratably, and (ii) Incremental Term Loans, ratably.

(b) Waivable Mandatory Prepayment. Anything contained herein to the contrary notwithstanding, in the event Borrower is required to make any mandatory prepayment (a "Waivable Mandatory Prepayment") of the Term Loans pursuant to Section 2.10 (other than Section 2.11(c)), not less than [***] prior to the date (the "Required Prepayment Date") on which Borrower is required to make such Waivable Mandatory Prepayment, Borrower shall notify Administrative Agent of the amount of such prepayment, and Administrative Agent will promptly thereafter notify each Lender holding an outstanding Term Loan of the amount of such Lender's Pro Rata Share of such Waivable Mandatory Prepayment and such Lender's option to refuse such amount. Each such Lender may exercise such option by giving written notice to Borrower and Administrative Agent of its election to do so on or before the [***] prior to the Required Prepayment Date (it being understood that any Lender which does not notify Borrower and Administrative Agent of its election to exercise such option on or before the [***] prior to the Required Prepayment Date shall be deemed to have elected, as of such date, not to exercise such option). On the Required Prepayment Date, Borrower shall pay to Administrative Agent the amount of the Waivable Mandatory Prepayment, which amount shall be applied (i) in an amount equal to that portion of the Waivable Mandatory Prepayment payable to those Lenders that have elected not to exercise such option, to prepay the Term Loans of such Lenders (which prepayment shall be applied in accordance with Section 2.11(a)), and (ii) to the extent of any excess, to Borrower for working capital and general corporate purposes.

(c) At any time an Application Event has occurred and is continuing, all payments shall be applied pursuant to Section 2.12(f). Nothing contained herein shall modify the provisions of Section 2.12(b) regarding the requirement that all prepayments be accompanied by accrued interest and fees on the principal amount being prepaid to the date of such prepayment and the applicable Applicable Premium, Prepayment Premium, or any requirement otherwise contained herein to pay all other amounts as the same become due and payable.

Section 2.12 General Provisions Regarding Payments.

(a) All payments by Borrower of principal, interest, fees and other Obligations shall be made in Dollars in immediately available funds, without defense, recoupment, setoff or counterclaim, free of any restriction or condition, and delivered to Administrative Agent, for the account of Lenders, not later than 1:00 p.m. (or such later time as the Administrative Agent may agree) on the date such payment is due and payable to Administrative Agent's Account. Funds received by Administrative Agent after that time on such due date may be deemed to have been paid by Borrower on the next Business Day.

(b) All payments in respect of the principal amount of any Term Loan shall be accompanied by payment of accrued interest on the principal amount being repaid or prepaid, any Prepayment Premium, any Applicable Premium, and all other amounts payable with respect to the principal amount being repaid or prepaid.

(c) Administrative Agent shall promptly distribute to each Lender at such address as such Lender shall indicate in writing, such Lender's applicable Pro Rata Share of all payments and prepayments of principal and interest due hereunder, together with all other amounts due with respect thereto, including, without limitation, all fees payable with respect thereto, to the extent received by Administrative Agent.

(d) Subject to the provisos set forth in the definition of "Interest Period", whenever any payment to be made hereunder shall be stated to be due on a day that is not a Business Day, such payment shall be made on the next succeeding Business Day and such extension of time shall be included in the computation of the payment of interest hereunder or of the commitment fees hereunder.

(e) Administrative Agent shall deem any payment by or on behalf of Borrower hereunder that is not made in same day funds prior to 1:00 p.m. (or such later time as the Administrative Agent may agree) to be a non-conforming payment. Any such payment shall be deemed not to have been received by Administrative Agent until the later of (i) the time such funds become available funds, and (ii) the applicable next Business Day. Administrative Agent shall give prompt telephonic notice to Borrower and each applicable Lender (confirmed in writing) if any payment is non-conforming. Any non-conforming payment may constitute or become a Default or Event of Default in accordance with the terms of Section 8.1(a). Interest shall continue to accrue on any principal as to which a non-conforming payment is made until such funds become available funds (but in no event less than the period from the date of such payment to the next succeeding applicable Business Day) at the Default Rate determined pursuant to Section 2.6 from the date such amount was due and payable until the date such amount is paid in full.

(f) At any time an Application Event has occurred and is continuing, or the maturity of the Obligations shall have been accelerated pursuant to Section 8.2, all payments or proceeds received by Administrative Agent hereunder or under any Collateral Document in respect of any of the Obligations, including, but not limited to all proceeds received by Administrative Agent in respect of any sale, any collection from, or other realization upon all or any part of the Collateral, shall be applied in full or in part as follows:

first, ratably to pay the Obligations in respect of any fees (other than any Prepayment Premium and Applicable Premium), expense reimbursements, indemnities and other amounts then due and payable to Administrative Agent until paid in full;

second, ratably to pay interest then due and payable in respect of Protective Advances until paid in full;

third, ratably to pay principal of Protective Advances then due and payable until paid in full;

fourth, ratably to pay the Obligations in respect of any fees (other than any Prepayment Premium and Applicable Premium) and indemnities then due and payable to the Lenders with a Term Loan Commitment until paid in full;

fifth, ratably to pay interest then due and payable in respect of the Term Loan until paid in full;

sixth, ratably to pay the principal of the Term Loan until paid in full;

seventh, ratably to pay the Obligations in respect of any Prepayment Premium and Applicable Premium then due and payable to the Lenders with a Term Loan Commitment until paid in full; and

eighth, to the ratable payment of all other Obligations then due and payable until paid in full.

(g) For purposes of Section 2.12(f) (other than clause *eighth* of Section 2.12(f)), “paid in full” means payment in cash of all amounts owing under the Loan Documents according to the terms thereof, including loan fees, service fees, professional fees, interest (and specifically including interest accrued after the commencement of any Insolvency Proceeding), default interest, interest on interest, and expense reimbursements, whether or not same would be or is allowed or disallowed in whole or in part in any Insolvency Proceeding, except to the extent that default or overdue interest (but not any other interest) and loan fees, each arising from or related to a default, are disallowed in any Insolvency Proceeding; provided, however, that for purposes of clause *eighth* of Section 2.12(f), “paid in full” means payment in cash of all amounts owing under the Loan Documents according to the terms thereof, including loan fees, service fees, professional fees, interest (and specifically including interest accrued after the commencement of any Insolvency Proceeding), default interest, interest on interest, and expense reimbursements, whether or not the same would be or is allowed or disallowed in whole or in part in any Insolvency Proceeding.

(h) In the event of a direct conflict between the priority provisions of Section 2.12(f) and other provisions contained in any other Loan Document, it is the intention of the parties hereto that both such priority provisions in such documents shall be read together and construed, to the fullest extent possible, to be in concert with each other. In the event of any actual, irreconcilable conflict that cannot be resolved as aforesaid, the terms and provisions of Section 2.12(f) shall control and govern.

(i) The Lenders and Borrower hereby authorize Administrative Agent to, and Administrative Agent may, from time to time, charge the Loan Account with any amount then due and payable by Borrower under any Loan Document. Each of the Lenders and Borrower agrees that Administrative Agent shall have the right to make such charges whether or not any Default or Event of Default shall have occurred and be continuing or whether any of the conditions precedent in Section 3.2 have been satisfied. Any amount charged to the Loan Account shall be deemed a Loan hereunder made by the Lenders to Borrower, funded by Administrative Agent on behalf of the Lenders and subject to Section 2.2. The Lenders and Borrower confirm that any charges that Administrative Agent may so make to the Loan Account as herein provided will be made as an accommodation to Borrower and solely at Administrative Agent’s discretion, provided that Administrative Agent shall from time to time in its discretion or upon the request of the Required Lenders, charge the Loan Account of Borrower with any amount due and payable under any Loan Document. The Administrative Agent shall provide a reasonably detailed invoice for any amounts charged to the Loan Account (unless such charge is made at the Borrower’s request) promptly upon request by the Borrower.

(j) Notwithstanding the foregoing provisions hereof, if any Conversion/Continuation Notice is withdrawn as to any Affected Lender or if any Affected Lender makes Base Rate Loans in lieu of its Pro Rata Share of any SOFR Loans, Administrative Agent shall give effect thereto in apportioning payments received thereafter.

Section 2.13 Ratable Sharing. Lenders hereby agree among themselves that, except as otherwise provided in the Collateral Documents with respect to amounts realized from the exercise of rights with respect to Liens on the Collateral, if any of them shall, whether by voluntary payment (other than a voluntary prepayment of Term Loans made and applied in accordance with the terms hereof), through the exercise of any right of set off or banker's lien, by counterclaim or cross action or by the enforcement of any right under the Loan Documents or otherwise, or as adequate protection of a deposit treated as cash collateral under the Bankruptcy Code, receive payment or reduction of a proportion of the aggregate amount of principal, interest, fees and other amounts then due and owing to such Lender hereunder or under the other Loan Documents (collectively, the "Aggregate Amounts Due" to such Lender) which is greater than the proportion received by any other Lender in respect of the Aggregate Amounts Due to such other Lender having Term Loans, then the Lender receiving such proportionately greater payment shall (a) notify Administrative Agent and each other Lender of the receipt of such payment and (b) apply a portion of such payment to purchase participations (which it shall be deemed to have purchased from each seller of a participation simultaneously upon the receipt by such seller of its portion of such payment) in the Aggregate Amounts Due to the other Lenders so that all such recoveries of Aggregate Amounts Due shall be shared by all Lenders having Term Loans in proportion to the Aggregate Amounts Due to them; provided, if all or part of such proportionately greater payment received by such purchasing Lender is thereafter recovered from such Lender upon the bankruptcy or reorganization of Borrower or otherwise, those purchases shall be rescinded and the purchase prices paid for such participations shall be returned to such purchasing Lender ratably to the extent of such recovery, but without interest. Borrower expressly consents to the foregoing arrangement and agrees that any holder of a participation so purchased may exercise any and all rights of banker's lien, set off or counterclaim with respect to any and all monies owing by Borrower to that holder with respect thereto as fully as if that holder were owed the amount of the participation held by that holder.

Section 2.14 Increased Costs; Capital Adequacy.

(a) Compensation For Increased Costs and Taxes. In the event that Administrative Agent or any Lender shall determine (which determination shall, absent manifest error, be final and conclusive and binding upon all parties hereto) that any law, treaty or governmental rule, regulation or order, or any change therein or in the interpretation, administration or application thereof (including the introduction of any new law, treaty or governmental rule, regulation or order), or any determination of a court or Governmental Authority, in each case that becomes effective after the date hereof, or compliance by Administrative Agent or such Lender with any guideline, request or directive issued or made after the date hereof by any central bank or other governmental or quasi-Governmental Authority (whether or not having the force of law): (i) subjects Administrative Agent or such Lender (or its applicable lending office) to any additional Tax (other than (A) Indemnified Taxes, (B) Taxes described in clauses (b) through (d) of the definition of Excluded Taxes and (C) Connection Income Taxes) with respect to its Loans, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto; (ii) imposes, modifies or holds applicable any reserve (including any marginal, emergency, supplemental, special or other reserve), special deposit, compulsory loan, FDIC insurance or similar requirement against assets held by, or deposits or other liabilities in or for the account of, or advances or loans by, or other credit extended by, or any other acquisition of funds by, any office of Administrative Agent or such Lender (other than any such reserve or other requirements with respect to SOFR Loans that are reflected in the definition of Term SOFR); or (iii) imposes any other condition (other than with respect to Taxes) on or affecting Administrative agent or such Lender (or its applicable lending office) or its obligations hereunder; and the result of any of the foregoing is to increase the cost to Administrative Agent or such Lender of agreeing to make, making or maintaining Loans hereunder or to reduce any amount received or receivable by Administrative Agent or such Lender (or its applicable lending office) with respect thereto; then, in any such case, Borrower shall promptly pay to Administrative Agent or such Lender, upon receipt of the statement referred to in the next sentence, such additional amount or amounts (in the form of an increased rate of, or a different method of calculating, interest or otherwise as Administrative Agent or such Lender in its sole discretion shall determine) as may be necessary to compensate Administrative Agent or such Lender for any such increased cost or reduction in amounts received or receivable hereunder. Administrative Agent or such Lender shall deliver to Borrower (with a copy to Administrative Agent, if applicable) a written statement, setting forth in reasonable detail the basis for calculating the additional amounts owed to Administrative Agent or such Lender under this Section 2.14(a), which statement shall be conclusive and binding upon all parties hereto absent manifest error.

(b) Capital Adequacy Adjustment. In the event that any Lender shall have determined that the adoption, effectiveness, phase in or applicability after the Closing Date of any law, rule or regulation (or any provision thereof) regarding capital adequacy, or any change therein or in the interpretation or administration thereof by any Governmental Authority, central bank or comparable agency charged with the interpretation or administration thereof, or compliance by any Lender (or its applicable lending office) with any guideline, request or directive regarding capital adequacy (whether or not having the force of law) of any such Governmental Authority, central bank or comparable agency, has or would have the effect of reducing the rate of return on the capital of such Lender or any corporation controlling such Lender as a consequence of, or with reference to, such Lender's Term Loans or other obligations hereunder with respect to the Term Loan to a level below that which such Lender or such controlling corporation could have achieved but for such adoption, effectiveness, phase in, applicability, change or compliance (taking into consideration the policies of such Lender or such controlling corporation with regard to capital adequacy), then from time to time, within [***] after receipt by Borrower from such Lender of the statement referred to in the next sentence, Borrower shall pay to such Lender such additional amount or amounts as will compensate such Lender or such controlling corporation on an after tax basis for such reduction. Such Lender shall deliver to Borrower (with a copy to Administrative Agent) a written statement, setting forth in reasonable detail the basis for calculating the additional amounts owed to Lender under this Section 2.14(b), which statement shall be conclusive and binding upon all parties hereto absent manifest error.

Section 2.15 Taxes; Withholding, Etc.

(a) Withholding of Taxes. All sums payable by any Loan Party hereunder and under the other Loan Documents shall (except to the extent required by applicable law) be paid free and clear of, and without any deduction or withholding on account of, any Tax. If any Loan Party or any other Person is required by law to make any deduction or withholding on account of any Tax with respect to any sum paid or payable by any Loan Party to Administrative Agent or any Lender under any of the Loan Documents: (1) Borrower shall notify Administrative Agent of any such requirement or any change in any such requirement as soon as Borrower becomes aware of it; (2) Borrower or the applicable Loan Party, if it is the applicable withholding agent, shall pay any such Tax before the date on which penalties attach thereto, such payment to be made (if the liability to pay is imposed on any Loan Party) for its own account or (if that liability is imposed on Administrative Agent or such Lender, as the case may be) on behalf of and in the name of Administrative Agent or such Lender; (3) if such Tax is an Indemnified Tax, then the sum payable by the applicable Loan Party shall be increased to the extent necessary to ensure that, after all such deductions or withholdings have been made by any applicable withholding agent (including any such deductions or withholdings applicable to additional sums payable under this Section 2.15), the applicable Lender (or, in the case of payments made to the Administrative Agent for its own account, the Administrative Agent) receives on the due date a net sum equal to what it would have received had no such deduction or withholding been required or made; and (4) within [***] days after paying any sum from which Borrower or any other Loan Party is required by law to make any deduction or withholding, Borrower shall deliver to Administrative Agent evidence satisfactory to Administrative Agent of such deduction or withholding and of the remittance thereof to the relevant Governmental Authority.

(b) Other Taxes. The Loan Parties shall pay to the relevant Governmental Authorities (or, at the option of Administrative Agent, timely reimburse it for the payment of) any present or future stamp, court, documentary, intangible, recording, filing or similar Taxes or any other property Taxes that arise from any payment made hereunder or from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, this Agreement or any other Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment ("Other Taxes"). Within [***] days after paying any such Other Taxes, each Loan Party shall deliver to Administrative Agent evidence satisfactory to Administrative Agent that such Other Taxes have been paid to the relevant Governmental Authority.

(c) Tax Indemnification.

(i) The Loan Parties hereby jointly and severally agree to indemnify and hold Administrative Agent and any Lender harmless from and against all Indemnified Taxes (including, without limitation, Indemnified Taxes imposed or asserted on or attributable to any amounts payable under this Section 2.15) payable or paid by such Person or required to be withheld or deducted with respect to any payment to such Person and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted; provided that if the Borrower reasonably believes that such Taxes were not correctly or legally asserted, the Administrative Agent or such Lender, as applicable, will, at the Borrower's request, use reasonable efforts to cooperate with the Borrower to obtain a refund of such Taxes (which shall be repaid to the Borrower in accordance with Section 2.15(e)) so long as such efforts would not, in the sole determination of the Administrative Agent or such Lender, result in any additional out-of-pocket costs or expenses not reimbursed by such Loan Party or be otherwise materially disadvantageous to the Administrative Agent or such Lender, as applicable. Such indemnification shall be paid within [***] days from the date on which Administrative Agent or Lender makes written demand therefor. A certificate as to the amount of such payment or liability delivered to Borrower by a Lender (with a copy to Administrative Agent), or by Administrative Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

(ii) Each Lender shall severally indemnify Administrative Agent, within [***] days after written demand therefor, for (i) any Indemnified Taxes attributable to such Lender (but only to the extent that the Loan Parties have not already indemnified Administrative Agent for such Indemnified Taxes and without limiting the obligation of the Loan Parties to do so), (ii) any Taxes attributable to such Lender's failure to comply with the provisions of Section 10.6(h)(ii) relating to the maintenance of a Participant Register and (iii) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by Administrative Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by Administrative Agent shall be conclusive absent manifest error. Each Lender hereby authorizes Administrative Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Administrative Agent to the Lender from any other source against any amount due to Administrative Agent under this paragraph.

(d) Evidence of Exemption From Withholding Tax.

(i) Any Lender that is entitled to any exemption from or reduction of withholding Tax with respect to any payments made under any Loan Document shall deliver to Borrower and Administrative Agent, at the time or times reasonably requested by Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by Borrower or Administrative Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Administrative Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Administrative Agent as will enable Borrower or Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 2.15(d)(i)(A), (i)(B) and (iii)) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. Without limiting the generality of the foregoing:

(A) any Lender that is a U.S. Person shall deliver to Borrower and Administrative Agent on or about the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Administrative Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

(B) any Foreign Lender shall, to the extent it is legally eligible to do so, deliver to Borrower and Administrative Agent (in such number of copies as shall be requested by the recipient) on or about the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Administrative Agent), whichever of the following is applicable:

(1) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to such tax treaty;

(2) executed copies of IRS Form W-8ECI;

(3) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Internal Revenue Code, (x) a certificate substantially in the form of Exhibit G-1 to the effect that such Foreign Lender is not a “bank” within the meaning of Section 881(c)(3)(A) of the Code, a “10 percent shareholder” of Borrower within the meaning of Section 871(h)(3)(B) of the Internal Revenue Code, or a “controlled foreign corporation” related to any Loan Party described in Section 881(c)(3)(C) of the Internal Revenue Code Internal Revenue Code (a “U.S. Tax Compliance Certificate”) and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

(4) to the extent a Foreign Lender is not the beneficial owner (for example, where the Foreign Lender is a partnership or a participating Lender), executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate substantially in the form of Exhibit G-2 or Exhibit G-3, IRS Form W-9, or other certification documents from each beneficial owner, as applicable; *provided* that if the Foreign Lender is a partnership (and not a participating Lender) and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of Exhibit G-4 on behalf of such direct and indirect partner(s);

(ii) any Foreign Lender shall, to the extent it is legally eligible to do so, deliver to Borrower and Administrative Agent (in such number of copies as shall be requested by the recipient) on or about the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Administrative Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower or Administrative Agent to determine the withholding or deduction required to be made; and

(iii) If a payment made to a Lender under any Loan Document would be subject to United States federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Internal Revenue Code, as applicable), such Lender shall deliver to Borrower and Administrative Agent at the time or times prescribed by law and at such time or times reasonably requested by Borrower or Administrative Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) and such additional documentation reasonably requested by Borrower or Administrative Agent as may be necessary for Borrower and Administrative Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount to deduct and withhold from such payment. Solely for purposes of this Section 2.15(d)(iii), FATCA shall include any amendments made to FATCA after the date of this Agreement.

(iv) Notwithstanding anything to the contrary in this Section 2.15(d), a Lender shall not be required to deliver any documentation pursuant to this Section 2.15(d) that such Lender is not legally eligible to deliver.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification, provide such successor form, or promptly notify the Borrower and the Administrative Agent in writing of its legal ineligibility to do so.

(e) Treatment of Certain Refunds. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 2.15 (including by the payment of additional amounts pursuant to this Section 2.15), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this Section 2.15 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 2.15(e) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 2.15(e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 2.15(e) the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This paragraph shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

Section 2.16 Obligation to Mitigate. Each Lender agrees that, as promptly as practicable after the officer of such Lender responsible for administering its Term Loans becomes aware of the occurrence of an event or the existence of a condition that would cause such Lender to become an Affected Lender or that would entitle such Lender to receive payments under Section 2.13, 2.14, 2.15 or 2.19, it will, to the extent not inconsistent with the internal policies of such Lender and any applicable legal or regulatory restrictions, use reasonable efforts to (a) make, issue, fund or maintain its Credit Extensions, including any Affected Loans, through another office of such Lender, or (b) take such other measures as such Lender may deem reasonable, if as a result thereof the circumstances that would cause such Lender to be an Affected Lender would cease to exist or the additional amounts that would otherwise be required to be paid to such Lender pursuant to Section 2.13, 2.14, 2.15 or 2.19 would be materially reduced and if, as determined by such Lender in its sole discretion, the making, issuing, funding or maintaining of such Term Loans through such other office or in accordance with such other measures, as the case may be, would not otherwise adversely affect such Term Loans or the interests of such Lender; provided, such Lender will not be obligated to take any of the foregoing measures pursuant to this Section 2.16 unless Borrower agrees to pay all incremental expenses incurred by such Lender as a result of taking such actions as described above. A certificate as to the amount of any such expenses payable by Borrower pursuant to this Section 2.16 (setting forth in reasonable detail the basis for requesting such amount) submitted by such Lender to Borrower (with a copy to Administrative Agent) shall be conclusive absent manifest error.

Section 2.17 Defaulting Lenders. Anything contained herein to the contrary notwithstanding, in the event that any Lender becomes the subject of a Bail-in Action or violates any provision of Section 9.5(c), or, other than at the direction or request of any regulatory agency or authority, defaults (in each case, a “Defaulting Lender”) in its obligation to fund (a “Funding Default”) a Term Loan (in each case, a “Defaulted Loan”), then (a) during any Default Period with respect to such Defaulting Lender, such Defaulting Lender shall be deemed not to be a “Lender” for purposes of voting on any matters (including the granting of any consents or waivers) with respect to any of the Loan Documents; and (b) to the extent permitted by applicable law, until such time as the Default Excess, if any, with respect to such Defaulting Lender shall have been reduced to zero, (i) any voluntary prepayment of the Term Loans shall, if Administrative Agent so directs at the time of making such voluntary prepayment, be applied to Term Loans of other Lenders as if such Defaulting Lender had no Term Loans outstanding and the outstanding Term Loans of such Defaulting Lender were zero, and (ii) any mandatory prepayment of the Term Loans shall, if Administrative Agent so directs at the time of making such mandatory prepayment, be applied to the Term Loans of other Lenders (but not to the Term Loans of such Defaulting Lender) as if such Defaulting Lender had funded all Defaulted Loans of such Defaulting Lender, it being understood and agreed that Borrower shall be entitled to retain any portion of any mandatory prepayment of the Term Loans that is not paid to such Defaulting Lender solely as a result of the operation of the provisions of this clause (b). No Term Loan Commitment of any Lender shall be increased or otherwise affected, and, except as otherwise expressly provided in this Section 2.17, performance by Borrower of its obligations hereunder and the other Loan Documents shall not be excused or otherwise modified as a result of any Funding Default or the operation of this Section 2.17. The rights and remedies against a Defaulting Lender under this Section 2.17 are in addition to other rights and remedies that Borrower may have against such Defaulting Lender with respect to any Funding Default and that Administrative Agent or any Lender may have against such Defaulting Lender with respect to any Funding Default or violation of Section 9.5(c).

Section 2.18 [Reserved].

Section 2.19 Making or Maintaining SOFR Loans.

(a) Inability to Determine Rates. Subject to Section 2.20, if, on or prior to the first day of any Interest Period for any SOFR Loan:

(i) the Administrative Agent determines (which determination shall be conclusive and binding absent manifest error) that reasonable and adequate means do not exist for ascertaining “Term SOFR” cannot be determined pursuant to the definition thereof, or

(ii) the Required Lenders determine that for any reason in connection with any request for a SOFR Loan or a conversion thereto or a continuation thereof that Term SOFR for any requested Interest Period with respect to a proposed SOFR Loan does not adequately and fairly reflect the cost to such Lenders of making and maintaining such Loan, and the Required Lenders have provided written notice of such determination to the Administrative Agent, then the Administrative Agent will promptly so notify Borrower and each Lender.

Upon notice thereof by the Administrative Agent to Borrower, any obligation of the Lenders to make SOFR Loans, and any right of Borrower to continue SOFR Loans or to convert Base Rate Loans to SOFR Loans, shall be suspended (to the extent of the affected SOFR Loans or affected Interest Periods) until the Administrative Agent (with respect to clause (b), at the instruction of the Required Lenders) revokes such notice. Upon receipt of such notice, (i) Borrower may revoke any pending request for a borrowing of, conversion to or continuation of SOFR Loans (to the extent of the affected SOFR Loans or affected Interest Periods) or, failing that, Borrower will be deemed to have converted any such request into a request for a borrowing of or conversion to Base Rate Loans in the amount specified therein and (ii) any outstanding affected SOFR Loans will be deemed to have been converted into Base Rate Loans at the end of the applicable Interest Period. Upon any such conversion, Borrower shall also pay accrued interest on the amount so converted, together with any additional amounts required pursuant to Section 2.19(c). Subject to Section 2.20, if the Administrative Agent determines (which determination shall be conclusive and binding absent manifest error) that “Term SOFR” cannot be determined pursuant to the definition thereof on any given day, the interest rate on Base Rate Loans shall be determined by the Administrative Agent without reference to clause (c) of the definition of “Base Rate” until the Administrative Agent revokes such determination.

(b) Illegality. If any Lender determines that any law has made it unlawful, or that any Governmental Authority has asserted that it is unlawful, for any Lender or its applicable lending office to make, maintain or fund Loans whose interest is determined by reference to SOFR, the Term SOFR Reference Rate or Term SOFR (the “Affected Loans”), or to determine or charge interest based upon SOFR, the Term SOFR Reference Rate or Term SOFR, then, upon notice thereof by such Lender (an “Affected Lender”) to Borrower (through the Administrative Agent) (an “Illegality Notice”), (a) any obligation of the Lenders to make SOFR Loans, and any right of Borrower to continue SOFR Loans or to convert Base Rate Loans to SOFR Loans, shall be suspended, and (b) the interest rate on which Base Rate Loans shall, if necessary to avoid such illegality, be determined by the Administrative Agent without reference to clause (c) of the definition of “Base Rate”, in each case until each Affected Lender notifies the Administrative Agent and Borrower that the circumstances giving rise to such determination no longer exist. Upon receipt of an Illegality Notice, Borrower shall, if necessary to avoid such illegality, upon demand from any Lender (with a copy to the Administrative Agent), prepay or, if applicable, convert all SOFR Loans to Base Rate Loans (the interest rate on which Base Rate Loans shall, if necessary to avoid such illegality, be determined by the Administrative Agent without reference to clause (c) of the definition of “Base Rate”), on the last day of the Interest Period therefor, if all affected Lenders may lawfully continue to maintain such SOFR Loans to such day, or immediately, if any Lender may not lawfully continue to maintain such SOFR Loans to such day, in each case until the Administrative Agent is advised in writing by each affected Lender that it is no longer illegal for such Lender to determine or charge interest rates based upon SOFR, the Term SOFR Reference Rate or Term SOFR. Upon any such prepayment or conversion, Borrower shall also pay accrued interest on the amount so prepaid or converted, together with any additional amounts required pursuant to Section 2.19(c).

(c) Compensation for Breakage or Non-Commencement of Interest Periods. Borrower shall compensate each Lender, upon written request by such Lender (which request shall set forth the basis for requesting such amounts), for all reasonable losses, expenses and liabilities (including any interest paid or calculated to be due and payable by such Lender to lenders of funds borrowed by it to make or carry its SOFR Loans and any loss, expense or liability sustained by such Lender in connection with the liquidation or re-employment of such funds but excluding loss of anticipated profits) that such Lender actually sustains: (i) if for any reason (other than a default by such Lender) a borrowing of any SOFR Loan does not occur on a date specified therefor in a Funding Notice, or a conversion to or continuation of any SOFR Loan does not occur on a date specified therefor in a Conversion/Continuation Notice for conversion or continuation; or (ii) if any prepayment or other principal payment of, or any conversion of, any of its SOFR Loans occurs on any day other than the last day of an Interest Period applicable to that Loan (whether voluntary, mandatory, automatic, by reason of acceleration, or otherwise).

(d) Booking of SOFR Loans. Any Lender may make, carry or transfer SOFR Loans at, to, or for the account of any of its branch offices or the office of an Affiliate of such Lender.

Section 2.20 Benchmark Replacement Setting.

(a) Benchmark Replacement. Notwithstanding anything to the contrary herein or in any other Loan Document, upon the occurrence of a Benchmark Transition Event, Administrative Agent and Borrower may amend this Agreement to replace the then-current Benchmark with a Benchmark Replacement. Any such amendment with respect to a Benchmark Transition Event will become effective at 5:00 p.m. on the [***]after Administrative Agent has posted such proposed amendment to all affected Lenders and Borrower so long as Administrative Agent has not received, by such time, written notice of objection to such amendment from Lenders comprising the Required Lenders. No replacement of a Benchmark with a Benchmark Replacement pursuant to this Section 2.20(a) will occur prior to the applicable Benchmark Transition Start Date.

(b) Benchmark Replacement Conforming Changes. In connection with the use, administration, adoption or implementation of a Benchmark Replacement, Administrative Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document other than the Administrative Agent and the Borrower.

(c) Notices; Standards for Decisions and Determinations. Administrative Agent will promptly notify the Borrower and the Lenders, in writing, of (1) the implementation of any Benchmark Replacement and (2) the effectiveness of any Conforming Changes in connection with the use, administration, adoption or implementation of a Benchmark Replacement. The Administrative Agent will notify Borrower of (x) the removal or reinstatement of any tenor of a Benchmark pursuant to Section 2.20(d) and (y) the commencement or conclusion of any Benchmark Unavailability Period. Any determination, decision or election that may be made by Administrative Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section 2.20, including any determination with respect to a tenor, rate or adjustment or of the occurrence or non-occurrence of an event, circumstance or date and any decision to take or refrain from taking any action or any selection, will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Loan Document, except, in each case, as expressly required pursuant to this Section 2.20.

(d) Unavailability of Tenor of Benchmark. Notwithstanding anything to the contrary herein or in any other Loan Document, at any time (including in connection with the implementation of a Benchmark Replacement), (1) if the then-current Benchmark is a term rate (including the Term SOFR) and either (I) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by Administrative Agent in its reasonable discretion or (II) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is not or will not be representative, then Administrative Agent may modify the definition of “Interest Period” (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non-representative tenor and (2) if a tenor that was removed pursuant to clause (1) above either (I) is subsequently displayed on a screen or information service for a Benchmark (including a Benchmark Replacement) or (II) is not, or is no longer, subject to an announcement that it is not or will not be representative for a Benchmark (including a Benchmark Replacement), then Administrative Agent may modify the definition of “Interest Period” (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor.

(e) Benchmark Unavailability Period. Upon Borrower’s receipt of notice of the commencement of a Benchmark Unavailability Period, (1) Borrower may revoke any pending request for a borrowing of, conversion to or continuation of SOFR Loans to be made, converted or continued during any Benchmark Unavailability Period and, failing that, Borrower will be deemed to have converted any such request into a request for a borrowing of or conversion to Base Rate Loans and (2) any outstanding affected SOFR Loans will be deemed to have been converted to Base Rate Loans at the end of the applicable Interest Period. During any Benchmark Unavailability Period or at any time that a tenor for the then-current Benchmark is not an Available Tenor, the component of the Base Rate based upon the then-current Benchmark or such tenor for such Benchmark, as applicable, will not be used in any determination of the Base Rate.

Section 2.21 Incremental Term Loans

Section 2.22 . After the Closing Date, the Borrower may, with the prior written consent of the Administrative Agent, on one or more occasions request additional term loans (“Incremental Term Loans”) by delivering notice to the Administrative Agent at least [***] prior to the requested Credit Date; provided, however, that:

(a) the aggregate amount of such Incremental Term Loans shall not exceed \$[***];

(b) the Lenders making such Incremental Term Loans have received investment committee approval (in such investment committee’s sole discretion) with respect thereto, and no Lender shall be obligated to provide any Incremental Term Loan Commitments or fund any Incremental Term Loan without its consent;

(c) any such Incremental Term Loan shall be in an amount not less than \$[***] (or such lesser amount then agreed to by the Administrative Agent);

(d) the conditions precedent set forth in Section 3.2 of the this Agreement shall have been satisfied as of the date such Incremental Term Loans are incurred (it being understood and agreed that the incurrence of such Incremental Term Loans shall not be subject to any other conditions precedent set forth in Section 3.2 of this Agreement, except to the extent agreed to by the Borrower and the Lenders providing such Incremental Term Loans);

(e) the terms and conditions with respect to any such Incremental Term Loans (including any fees payable in connection therewith) shall be set forth in the applicable Incremental Amendment with respect thereto; provided, however, that:

(i) the final maturity date of such Incremental Term Loans shall be no earlier than the Latest Maturity Date of the then outstanding Term Loans;

(ii) the Weighted Average Life to Maturity of such Incremental Term Loans shall be no shorter than the remaining Weighted Average Life to Maturity of the then outstanding Term Loans (determined without giving effect to any prepayments that reduce amortization or that would otherwise modify the Weighted Average Life to Maturity);

(iii) such Incremental Term Loans may participate on a pro rata basis or a less than pro rata basis (but not greater than a pro rata basis) in any voluntary or mandatory repayments or prepayments of the Term Loans;

(iv) such Incremental Term Loans (A) shall rank *pari passu* in right of payment and with respect to security with the Obligations, (B) may not be secured by any assets other than the Collateral and (C) may not be guaranteed by any Person that is not a Loan Party;

(f) except as otherwise expressly permitted in this Section 2.21 (and except for any terms and conditions with respect to any Incremental Term Loans that are applicable only after the Latest Maturity Date of the then outstanding Term Loans), the terms and conditions with respect to any Incremental Term Loans shall not be (A) materially more favorable to the Lenders of such Incremental Term Loans than the existing terms and conditions contained in the Loan Documents that apply to the Lenders of the then outstanding Term Loans (unless such existing terms and conditions contained in the Loan Documents are amended so as to conform to the materially more favorable terms and conditions that apply to the Lenders of the Incremental Term Loans) or (B) materially adverse to the Lenders of the then outstanding Term Loans (in their capacity as such Lenders); and

(g) the commitments in respect of such Incremental Term Loans (the “Incremental Term Loan Commitments”) shall become Term Loan Commitments hereunder pursuant to an amendment (an “Incremental Amendment”) to this Agreement and, as appropriate, the other Loan Documents, executed by the Borrower, each existing Lender agreeing to provide such Term Loan Commitment, if any, each additional Lender agreeing to provide such Commitment, if any, and the Administrative Agent. The Incremental Amendment may, without the consent of any other Lenders, effect such amendments to this Agreement and the other Loan Documents as may be necessary or appropriate, in the reasonable opinion of the Administrative Agent and the Borrower, to effect the provisions of this Section 2.21.

ARTICLE III

CONDITIONS PRECEDENT

Section 3.1 Closing Date. The effectiveness of this Agreement, and the obligation of each Lender to make a Credit Extension on the Initial Funding Date, is subject to the satisfaction, or waiver in accordance with Section 10.5, of the following conditions on or before the Closing Date:

(a) Loan Documents. Administrative Agent shall have received copies of each Loan Document duly executed and delivered by each applicable Loan Party for each Lender.

(b) Organizational Documents; Incumbency. Administrative Agent shall have received a Secretary’s or Director’s Certificate for each Loan Party attaching (i) copies of each Organizational Document of such Loan Party and, to the extent applicable, certified as of a recent date by the appropriate governmental official, each dated the Closing Date or a recent date prior thereto; (ii) signature and incumbency certificates of the officers or directors of such Person executing the Loan Documents to which it is a party; (iii) resolutions of the Board of Directors or similar governing body of such Loan Party approving and authorizing the execution, delivery and performance of this Agreement and the other Loan Documents to which it is a party or by which it or its assets may be bound as of the Closing Date, certified as of the Closing Date by its secretary, assistant secretary or a director as being in full force and effect without modification or amendment; and (iv) a good standing certificate (to the extent such concept exists) from the applicable Governmental Authority of such Loan Party’s jurisdiction of incorporation, organization or formation, each dated a recent date prior to the Closing Date.

(c) Organizational and Capital Structure. The organizational structure and capital structure of Borrower and its Subsidiaries shall be as set forth on Schedule 4.2.

(d) Governmental Authorizations and Consents. Each Loan Party shall have obtained all Governmental Authorizations and all consents of other Persons, in each case that are necessary or advisable in connection with the transactions contemplated by the Loan Documents and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to Administrative Agent. All applicable waiting periods shall have expired without any action being taken or threatened by any competent authority that would restrain, prevent or otherwise impose adverse conditions on the transactions contemplated by the Loan Documents or the financing thereof and no action, request for stay, petition for review or rehearing, reconsideration, or appeal with respect to any of the foregoing shall be pending, and the time for any applicable agency to take action to set aside its consent on its own motion shall have expired.

(e) Personal Property Collateral. In order to create in favor of Administrative Agent, for the benefit of Secured Parties, a valid, perfected First Priority security interest in the personal property Collateral, Administrative Agent shall have received:

(i) evidence satisfactory to Administrative Agent of the compliance by each Loan Party of their obligations under the Pledge and Security Agreement and the other Collateral Documents (including, without limitation, their obligations to authorize or execute, as the case may be, and deliver UCC financing statements, originals of Capital Stock (including stock certificates, if any, representing pledged Capital Stock along with appropriate endorsements), instruments and chattel paper, and any agreements governing deposit or securities accounts as provided therein), together with appropriate financing statements on Form UCC-1 in form for filing in such office or offices as may be necessary or, in the opinion of Administrative Agent, desirable to perfect the security interests purported to be created by each Pledge and Security Agreement and each other Collateral Document;

(ii) a completed Perfection Certificate dated the Closing Date and executed by an Authorized Officer of each Loan Party, together with all attachments contemplated thereby, including (A) the results of a recent search, by a Person satisfactory to Administrative Agent, of all effective UCC financing statements (or equivalent filings) made with respect to any assets or property of any Loan Party in the jurisdictions specified in the Perfection Certificate, together with copies of all such filings disclosed by such search, and (B) UCC termination statements (or similar documents) duly executed by all applicable Persons for filing in all applicable jurisdictions as may be necessary to terminate any effective UCC financing statements (or equivalent filings) disclosed in such search (other than any such financing statements in respect of Permitted Liens); and

(f) Financial Statements; Forecast. Lenders shall have received from Borrower (i) the Historical Financial Statements and (ii) the Forecast.

(g) Evidence of Insurance. The Administrative Agent shall have received a certificate from Borrower's insurance broker or other evidence reasonably satisfactory to it that all insurance required to be maintained pursuant to Section 5.5 is in full force and effect, in form and substance reasonably satisfactory to Administrative Agent.

(h) Opinion of Counsel to Loan Parties. Lenders and their respective counsel shall have received an executed copy of the favorable written opinions of Ropes & Gray LLP, counsel for Loan Parties, as to such other matters as Administrative Agent may reasonably request, dated the Closing Date and otherwise in form and substance reasonably satisfactory to Administrative Agent.

(i) Fees. Borrower shall have paid to Administrative Agent, the fees and expenses then due and payable pursuant to Section 2.7 and Section 10.2.

(j) Solvency Certificate. On the Closing Date, Administrative Agent shall have received a duly executed Solvency Certificate of the chief financial officer of Borrower, dated as of the Closing Date and addressed to Administrative Agent and Lenders, and in form, scope and substance satisfactory to Administrative Agent, certifying that after giving effect to the consummation of the transactions contemplated herein including the funding of the Initial Term Loan on the Initial Funding Date, Borrower and its Subsidiaries are and will be Solvent.

(k) Closing Date Certificate. Borrower shall have delivered to Administrative Agent a duly executed Closing Date Certificate, together with all attachments thereto.

(l) No Litigation. There shall not exist any action, suit, investigation, litigation or proceeding or other legal or regulatory developments, pending or threatened in any court or before any arbitrator or Governmental Authority that singly or in the aggregate materially impairs the transactions contemplated by the Loan Documents or that would reasonably be expected to have a Material Adverse Effect.

(m) [Reserved].

(n) No Material Adverse Effect/Material Regulatory Liability. Since [***], no event, circumstance or change shall have occurred that has caused or evidences, either in any case or in the aggregate, a Material Adverse Effect or a Material Regulatory Liability.

(o) Completion of Proceedings. All partnership, corporate and other proceedings taken or to be taken in connection with the transactions contemplated hereby and all documents incidental thereto not previously found acceptable by Administrative Agent and its counsel shall be satisfactory in form and substance to Administrative Agent and such counsel, and Administrative Agent.

(p) Bank Regulations. Administrative Agent shall have received all documentation and other information reasonably requested that is required by bank regulatory authorities under applicable “know-your-customer” and anti-money laundering rules and regulations, including the Patriot Act, and all such documentation and other information shall be in form and substance reasonably satisfactory to Administrative Agent.

(q) [Reserved].

(r) Representations and Warranties. The representations and warranties contained herein and in each other Loan Document, certificate or other writing delivered to Administrative Agent or any Lender pursuant hereto or thereto on or prior to the date hereof shall be true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to “materiality” or “Material Adverse Effect” in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as the date hereof to the same extent as though made on and as of that date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to “materiality” or “Material Adverse Effect” in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date.

(s) No Default or Event of Default. No event shall have occurred and be continuing or would result from the consummation of the transactions contemplated herein that would constitute an Event of Default or a Default.

(t) Registrations. All Registrations from the FDA and EMA in respect of the Products shall be valid and subsisting and in full force and effect.

Each Lender, by delivering its signature page to this Agreement, shall be deemed to have acknowledged receipt of, and consented to and approved, each Loan Document and each other document or item required to be approved by or satisfactory to Administrative Agent, Required Lenders or Lenders, as applicable, on the Closing Date.

Section 3.2 Conditions to Each Credit Extension

(a) . The obligation of each Lender to make the Initial Term Loan on the Initial Funding Date or any other Loan on any date following the Closing Date is subject to the satisfaction, or waiver in accordance with Section 10.5, of the following conditions precedent:

(a) Funding Notice. Administrative Agent shall have received a fully executed and delivered Funding Notice as and when required by Section 2.1(b)(i).

(b) Representations and Warranties. As of as of the applicable Credit Date, the representations and warranties contained herein and in each other Loan Document, certificate or other writing delivered to the Administrative Agent or any Lender pursuant hereto or thereto on or prior to the Credit Date shall be true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to “materiality” or “Material Adverse Effect” in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of that Credit Date to the same extent as though made on and as of that date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to “materiality” or “Material Adverse Effect” in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date;

(c) No Default or Event of Default. As of as of the applicable Credit Date, no event shall have occurred and be continuing or would result from the consummation of the applicable Credit Extension that would constitute an Event of Default or a Default;

(d) Minimum Qualified Cash. With respect to the Initial Funding Date, Administrative Agent shall have received evidence reasonably satisfactory to it that the Loan Parties shall have Qualified Cash of at least \$[***] on the Initial Funding Date (on a pro forma basis after giving effect to the Credit Extension made on the Initial Funding Date, the Closing Date Refinancing and the payment of all Transaction Costs required to be paid in Cash).

(e) Fees. On each Credit Date, the Loan Parties shall have paid all fees, costs and expenses then payable by the Loan Parties pursuant to this Agreement and the other Loan Documents, including, without limitation, Section 2.7, and Section 10.2 hereof.

(f) Lender Approval. With respect to any Incremental Term Loans, the funding of such Term Loan shall have been approved by each applicable Lender in its sole and absolute discretion.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES

In order to induce the Administrative Agent and Lenders to enter into this Agreement and to make each Credit Extension to be made thereby, each Loan Party represents and warrants to the Administrative Agent and Lender, on the Closing Date and on each Credit Date, that the following statements are true and correct:

Section 4.1 Organization; Requisite Power and Authority; Qualification. Each of Borrower and its Subsidiaries (a) is duly organized or incorporated, validly existing and in good standing under the laws of its jurisdiction of organization or incorporation as identified in Schedule 4.1, (b) has all requisite power and authority to own and operate its properties, to carry on its business as now conducted and as proposed to be conducted, to enter into the Loan Documents to which it is a party and to carry out the transactions contemplated thereby and, in the case of Borrower, to make the borrowings hereunder, and (c) is qualified to do business and in good standing in every jurisdiction where its assets are located and wherever necessary to carry out its business and operations, except in jurisdictions where the failure to be so qualified or in good standing has not had, and would not be reasonably expected to have, a Material Adverse Effect.

Section 4.2 Capital Stock and Ownership. The Capital Stock of each of Borrower and its Subsidiaries has been duly authorized and validly issued and is fully paid and non-assessable. Except as set forth on Schedule 4.2, as of the date hereof, there is no existing option, warrant, call, right, commitment or other agreement to which Borrower or any Subsidiary of Borrower is a party requiring, and there is no membership interest or other Capital Stock of such Subsidiary outstanding which upon conversion or exchange would require, the issuance by Borrower or any of its Subsidiaries of any additional membership interests or other Capital Stock of Borrower or any of its Subsidiaries or other securities convertible into, exchangeable for or evidencing the right to subscribe for or purchase, a membership interest or other Capital Stock of Borrower or any of its Subsidiaries. Schedule 4.2 correctly sets forth the ownership interest of Borrower and each of its Subsidiaries in their respective Subsidiaries as of the Closing Date.

Section 4.3 Due Authorization. The execution, delivery and performance of the Loan Documents and the consummation by each Loan Party of the transactions contemplated hereby and by the other Loan Documents have been duly authorized by all necessary action on the part of each Loan Party that is a party thereto.

Section 4.4 No Conflict. The execution, delivery and performance by Loan Parties of the Loan Documents to which they are parties and the consummation of the transactions contemplated by the Loan Documents do not and will not (a) violate any provision of (i) any law or any governmental rule or regulation applicable to Borrower or any of its Subsidiaries, (ii) any of the Organizational Documents of Borrower or any of its Subsidiaries, or (iii) any order, judgment or decree of any court or other agency of government binding on Borrower or any of its Subsidiaries, except, in the cases of clauses (a)(i) and (a)(iii), as would not reasonably be expected to result in a Material Adverse Effect; (b) conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any Material Contract; (c) result in or require the creation or imposition of any Lien upon any of the properties or assets of Borrower or any of its Subsidiaries (other than any Liens created under any of the Loan Documents in favor of Administrative Agent, on behalf of Secured Parties); (d) result in any default, non-compliance, suspension revocation, impairment, forfeiture or non-renewal of any permit, license, authorization or approval applicable to its operations or any of its properties except as would not reasonably be expected to result in a Material Adverse Effect; or (e) require any approval of stockholders, members or partners or any approval or consent of any Person under any Material Contract, except for such approvals or consents that will be obtained on or before the Closing Date and disclosed in writing to Lenders.

Section 4.5 Governmental Consents. The execution, delivery and performance by Loan Parties of the Loan Documents to which they are parties and the consummation of the transactions contemplated by the Loan Documents do not and will not require any registration with, consent or approval of, or notice to, or other action to, with or by, any Governmental Authority except for filings and recordings with respect to the Collateral to be made, or otherwise delivered to Administrative Agent for filing or recordation, as of the Closing Date.

Section 4.6 Binding Obligation. Each Loan Document has been duly executed and delivered by each Loan Party that is a party thereto and is the legally valid and binding obligation of such Loan Party, enforceable against such Loan Party in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability.

Section 4.7 Historical Financial Statements. The Historical Financial Statements were prepared in conformity with GAAP and fairly present, in all material respects, the financial position, on a consolidated basis, of the Persons described in such financial statements as at the respective dates thereof and the results of operations and cash flows, on a consolidated basis, of the entities described therein for each of the periods then ended, subject, in the case of any such unaudited financial statements, to changes resulting from audit and normal year end adjustments and the absence of footnotes. As of the Closing Date, neither Borrower nor any of its Subsidiaries has any contingent liability or liability for taxes, long term lease or unusual forward or long term commitment that is not reflected in the Historical Financial Statements or the notes thereto and which in any such case is material in relation to the business, operations, properties, assets and, condition (financial or otherwise) of the Borrower and any of its Subsidiaries taken as a whole.

Section 4.8 Forecasts. The revenue forecast of Borrower and its Subsidiaries for the period of [***] through and including [***] (the "Forecast") is based on good faith estimates and assumptions made by the management of Borrower; provided, the Forecast is not to be viewed as facts and that actual results during the period or periods covered by the Forecast may differ from such Forecast and that the differences may be material; provided, further, as of the Closing Date, management of Borrower believed that the Forecast was reasonable.

Section 4.9 No Material Adverse Effect. Since [***], no event, circumstance or change has occurred that has caused or evidences, either in any case or in the aggregate, a Material Adverse Effect.

Section 4.10 Adverse Proceedings, Etc. There are no Adverse Proceedings that (a) relate to any Loan Document or the transactions contemplated hereby or thereby or (b) individually or in the aggregate, would materially impair Administrative Agent's security interest in the Collateral, Borrower's and its Subsidiaries' respective rights, powers or remedies with respect to applicable Products or could otherwise reasonably be expected to have a Material Adverse Effect. Neither Borrower nor any of its Subsidiaries is subject to or in default with respect to any final judgments, writs, injunctions, decrees, rules, laws or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign except to the extent such default could not reasonably be expected to result in a Material Adverse Effect.

Section 4.11 Payment of Taxes. All U.S. federal income Tax returns and all other material Tax returns and reports required to have been filed by or with respect to Borrower or any of its Subsidiaries have been timely filed, and all U.S. federal income and all other material Taxes imposed on Borrower or any of its Subsidiaries (including in their capacity as a withholding agent), or with respect to their respective properties, assets, income, businesses and franchises, that have become due and payable have been paid when due and payable, except for Taxes that are being contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves are being maintained in accordance with GAAP. Except as otherwise set forth on Schedule 4.11, there is no ongoing or, to the knowledge of Borrower, proposed or threatened Tax assessment, deficiency, audit or other proceeding against Borrower or any of its Subsidiaries. Notwithstanding the foregoing, in the case of any Credit Date, matters occurring after the Closing Date that are permitted under Section 5.3 shall not violate this Section 4.11 with respect to such Credit Date.

Section 4.12 Properties, Title. Each of Borrower and its Subsidiaries has (a) good, sufficient, marketable and legal title to (in the case of fee interests in real property), (b) valid leasehold interests in (in the case of leasehold interests in real or personal property), and (c) good and valid title to (in the case of all other personal property), all of their respective properties and assets reflected in their respective Historical Financial Statements referred to in Section 4.7 and in the most recent financial statements delivered pursuant to Section 5.1, in each case except for (i) assets disposed of since the date of such financial statements in the ordinary course of business or as otherwise permitted under Section 6.9 or (ii) defects in title or interests that would not, individually or in the aggregate, reasonably be expected to interfere with the Borrower or its applicable Subsidiary's ability to conduct its business as currently conducted or utilize such property for its intended purpose. All such properties and assets are in working order and condition, ordinary wear and tear excepted, and except as permitted by this Agreement, all such properties and assets are free and clear of Liens (other than Permitted Liens). As of the Closing Date, Schedule 4.12 contains a true, accurate and complete list of all property owned or leased by Borrower and its Subsidiaries or where Collateral having an aggregate fair market value (reasonably determined in good faith by an Authorized Officer of Borrower) in excess of \$[***] or books and records are located.

Section 4.13 Environmental Matters. Except as any such failure could not reasonably be expected to result in a Material Adverse Effect:

(a) No Environmental Claim has been asserted against any Loan Party or any predecessor in interest nor has any Loan Party received written notice of any threatened or pending Environmental Claim against Loan Party or any predecessor in interest.

(b) There has been no Release of Hazardous Materials and there are no Hazardous Materials present in violation of Environmental Law at any of the properties currently owned or operated by any Loan Party.

(c) The operation of the business of, and each of the properties owned or operated by, each Loan Party are in compliance with all Environmental Laws.

(d) Each Loan Party holds, and is in compliance with those Governmental Authorizations required under any Environmental Laws in connection with the operations carried on by it and the properties owned or operated by it.

Section 4.14 No Defaults. Neither Borrower nor any of its Subsidiaries is in default in the performance, observance or fulfillment of any of the obligations, covenants or conditions contained in any of its Contractual Obligations, and no condition exists that, with the giving of notice or the lapse of time or both, could constitute such a default, except, in each case, where the consequences, direct or indirect, of such default or defaults, if any, could not reasonably be expected to have a Material Adverse Effect.

Section 4.15 Material Contracts. Schedule 4.15 contains a true, correct and complete list of all the Material Contracts in effect on the Closing Date, together with any updates provided pursuant to Section 5.1(l). All such Material Contracts are in full force and effect and no defaults currently exist thereunder (other than as described in Schedule 4.15 or in such updates). Each Material Contract is a legal, valid and binding obligation of Borrower or its Subsidiaries and, to the knowledge of Borrower, each other party thereto, is enforceable in accordance with its terms and is in full force and effect, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles. Neither Borrower nor its Subsidiaries, nor, to the knowledge of Borrower or its Subsidiaries, any other party to any Material Contract is in material breach or default under the terms of any Material Contract, and no condition exists that, with the giving of notice or the lapse of time or both, would constitute a breach or default by Borrower or any of its Subsidiaries thereunder that could result in any material liability to Borrower or such Subsidiary or termination of such Material Contract.

Section 4.16 Governmental Regulation. Neither Borrower nor any of its Subsidiaries is subject to regulation under the Public Utility Holding Company Act of 2005, the Federal Power Act or the Investment Company Act of 1940 or under any other federal or state statute or regulation that may limit its ability to incur Indebtedness or that may otherwise render all or any portion of the Obligations unenforceable. Neither Borrower nor any of its Subsidiaries is a "registered investment company" or a company "controlled" by a "registered investment company" or a "principal underwriter" of a "registered investment company" as such terms are defined in the Investment Company Act of 1940.

Section 4.17 Margin Stock. Neither Borrower nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of extending credit for the purpose of purchasing or carrying any Margin Stock. No part of the proceeds of the Term Loans made to such Loan Party will be used to purchase or carry any such Margin Stock or to extend credit to others for the purpose of purchasing or carrying any such Margin Stock or for any purpose that violates, or is inconsistent with, the provisions of Regulation T, U or X of the Board of Governors of the Federal Reserve System or any similar regulation in any other jurisdiction.

Section 4.18 Employee Benefit Plans. No ERISA Event has occurred or is reasonably expected to occur that has resulted or could reasonably be expected to result in a Material Adverse Effect or result in the imposition of a Lien.

Section 4.19 Certain Fees. Except as disclosed to Administrative Agent prior to the Closing Date, no broker's or finder's fee or commission will be payable with respect hereto or any of the transactions contemplated hereby.

Section 4.20 Solvency. Borrower is individually, and the Loan Parties and their Subsidiaries on a consolidated basis are, and upon the occurrence of the Credit Extension by the Borrower on the Closing Date and on each Credit Date will be, Solvent.

Section 4.21 ERISA. The underlying assets of Borrower and its Subsidiaries do not constitute "plan assets" within the meaning of 29 CFR §2510.3-101 et seq., as modified by Section 3(42) of ERISA (the "Plan Assets Regulation" or any similar applicable law) of one or more Benefit Plans. Assuming for purposes of this Section 4.21 that the Lender is not, and will not be, using "plan assets" in connection with this Agreement, the execution, delivery and performance of this Agreement and the other Loan Documents do not and will not constitute a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Internal Revenue Code.

Section 4.22 Compliance with Statutes, Etc.

Each of Borrower and its Subsidiaries is in compliance with (i) its Organizational Documents and (ii) all applicable laws, statutes, regulations and orders of, and all applicable restrictions imposed by, all Governmental Authorities, in respect of the conduct of its business and the ownership of its property, except such non-compliance that, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect.

Section 4.23 Intellectual Property.

(a) To the knowledge of Borrower and its Subsidiaries, each of the Borrower or its Subsidiaries own, or hold valid licenses in, all the Intellectual Property Rights that are necessary to the conduct of Borrower's and its Subsidiaries' business as currently conducted, including the research, discovery, development, manufacture, use, and Commercialization of the Products, except, in the case of any Product (Non-Core), where such infringement or misappropriation would not reasonably be expected to result in a Material Adverse Effect. Except as set forth in Schedule 4.23(a), and except as set forth in the License Agreements, to the knowledge of Borrower and its Subsidiaries, Borrower and its Subsidiaries have the exclusive right and license to manufacture, use and Commercialize the Products under the Product Intellectual Property Rights, the Registrations, and the regulatory documentation. The claims in US 11,807,689, US 11,814,439, and US 11,884,740 cover the Product (Core). US 11,807,689, US 11,814,439, and US 11,884,740 are jointly owned by Laboratoire Francais Du Fractionnement Et Des Biotechnologies, Les Ulis (FR) and the Borrower, and the subject matter disclosed and claimed in these patents are considered joint improvements under the BRIUMVI License Agreement. The Borrower has (i) an exclusive, fully paid-up, irrevocable right to use the joint improvements under BRIUMVI License Agreement, and (ii) the exclusive right to commercialize, use, have used, manufacture, have manufactured, supply, sell, offer to sell, and import the Products covered by the claims of US 11,807,689, US 11,814,439, and US 11,884,740. LFB has no outstanding rights in these patents.

(b) Schedule 4.23(b) sets forth a true, correct and complete listing as of the date hereof, under separate headings, of all Contractual Obligations (i) under which Borrower or its Subsidiaries is granted a license or right to use any Product Intellectual Property Rights that any other Person owns, or owes any royalties or other payments to any Person for the use of any Product Intellectual Property Rights, (ii) under which Borrower or its Subsidiaries have granted any Person any right or interest in any Product Intellectual Property Rights (excluding rights granted to third parties acting for the benefit of Borrower, including contract research organizations or contract manufacturing organizations), or (iii) that are necessary or material for Borrower or its Subsidiaries' use of or rights in the Product Intellectual Property Rights (including covenants not to sue), except, in the case of Contractual Obligations relating solely to any Product (Non-Core), where such Contractual Obligations are not material to the research, development, use, import or Commercialization of such Product (collectively, "License Agreements"). As of the date hereof, each License Agreement identified on Schedule 4.23(b) is a valid and binding obligation of Borrower or Subsidiary, as applicable, and to the knowledge of Borrower or the applicable Subsidiary that is party to such License Agreement, the counterpart(ies) thereto and is enforceable against each counterparty thereto in accordance with its terms, except as may be limited by applicable bankruptcy laws or by general principles of equity (whether considered in a proceeding in equity or at law). Neither Borrower nor any of its Subsidiaries has received any written notice in connection with any such License Agreement challenging the validity, enforceability or interpretation of any provision of such agreement. Neither Borrower nor any of its Subsidiaries has (A) given written notice to a counterparty of the termination of any such License Agreement (whether in whole or in part) or any written notice to a counterparty expressing any intention to terminate any such License Agreement or (B) received from a counterparty thereto any written notice of termination of any such License Agreement (whether in whole or in part) or any written notice from a counterparty stating its intention to terminate any such License Agreement. Neither Borrower nor any of its Subsidiaries has consented to any assignment by the counterparty to any License Agreement of any of its rights or obligations under any such License Agreement, and, to the knowledge of Borrower or the applicable Subsidiary that is party to a License Agreement, the counterparty has not assigned any of its rights or obligations under any such License Agreement to any Person. Neither Borrower nor any of its Subsidiaries has notified in writing the respective counterparty to any License Agreement or any other Person of any claims for indemnification under any License Agreement nor has Borrower or any Subsidiary received any written claims for indemnification under any License Agreement. Neither Borrower nor any Subsidiary has received any written notice from, or given any written notice to, any counterparty to any License Agreement alleging any infringement of any of the Patents licensed thereunder.

(c) As of the date hereof, Schedule 4.23(c) sets forth:

(i) a true, correct and complete listing, including owner and registration or application number, of all the Product Intellectual Property Rights related to the Product (Core) that are U.S. (federal or state) and foreign Patents, and identifies the owner of each such patent/application; provided, however, that such Patents in-licensed by Borrower or its Subsidiaries from a third party are listed as of the date such Borrower or Affiliate entered into the applicable in-license agreement. Except as identified in Schedule 4.23(c)(i), the owner listed on Schedule 4.23(c)(i) is the exclusive owner of such patent, registration or application. To the knowledge of Borrower and its Subsidiaries, in each issued Patent listed on Schedule 4.23(c)(i), there is at least one valid claim that would be infringed by the use, manufacture, or Commercialization of a Product (Core),

(ii) a true, correct and complete listing, including registration or application number, of all the Product Intellectual Property Rights related to the Product (Non-Core) that are U.S. (federal or state) and foreign Patents; provided, however, that such Patents controlled by Borrower or its Subsidiaries pursuant to an agreement with a third party are listed as of the date such Borrower or Affiliate entered into the applicable agreement. To the knowledge of Borrower and its Subsidiaries, as of the date such Borrower or Affiliate entered into the applicable in-license agreement, each Patent listed on Schedule 4.23(c)(ii) is owned or exclusively controlled by the third party that is party to the applicable license agreement,

(iii) a true, correct and complete listing, including owner and registration or application number, of all the Product Intellectual Property Rights that are U.S. (federal or state) and foreign registered trademarks and trademark applications,

(iv) a true, correct and complete listing, including owner and registration or application number, of all the Product Intellectual Property Rights that are U.S. (federal or state) and foreign registered copyrights and copyright applications,

(v) a true, correct and complete listing, including owner, of all the Product Intellectual Property Rights that are U.S. (federal or state) and foreign domain names, and

(vi) any other form of registered Product Intellectual Property Rights.

Except as identified in Schedule 4.23(c), (i) to the knowledge of Borrower and its Subsidiaries, such Patents and registrations are valid, subsisting and enforceable; (ii) none of the patents, registrations or applications owned by Borrower nor, to the knowledge of Borrower, in-licensed patents, registrations or applications have lapsed or been abandoned, cancelled or expired, except for patents, registrations or applications abandoned in the ordinary course of business; (iii) Borrower has or, to the knowledge of Borrower, the owner of any in-licensed patents, registrations or applications has, taken all reasonable steps to maintain such patents, registrations or applications, including by timely paying fees and filing responses; and (iv) to the knowledge of Borrower and its Subsidiaries, each individual associated with the filing and prosecution of such patents, registrations or applications, including the named inventors in the case of the Product Patents, has complied in all material respects with all applicable duties of candor and good faith in dealing with any patent office, including the USPTO, in those jurisdictions where such duties exist. Borrower may update Schedule 4.23(c) to add additional patents, registrations or applications, so long as such amendment occurs by written notice to Administrative Agent, subject to Borrower's obligations and restrictions under this Agreement.

(d) None of Borrower or any of its Subsidiaries (A) is a party to any pending opposition, reexamination, inter partes review, post-grant review, interference, derivation or other post-grant proceeding, injunction, claim, suit, action, subpoena, hearing, inquiry, investigation (by the International Trade Commission or otherwise), complaint, arbitration, mediation, demand, decree or other dispute, disagreement, proceeding or claim (collectively, “Disputes”) or (B) has received written notice of any threat of any Dispute, in each case ((A) and (B)), that challenges the legality, scope, validity, enforceability, infringement, ownership, inventorship or other rights with respect to any of the Product Intellectual Property Rights that are owned by Borrower or its Subsidiaries, and to the knowledge of Borrower and its Subsidiaries there are no facts that could provide a reasonable basis for such a claim. Borrower and its Subsidiaries have not received any written notice that there is any, and to their knowledge there is no, Person who is or claims to be an inventor under any of the Product Patents who is not a named inventor thereof.

(e) To the knowledge of Borrower and its Subsidiaries, no owner of any in-licensed Intellectual Property Rights is a party to any pending Dispute, or has received written notice of any threat of any Dispute, that challenges the legality, scope, validity, enforceability, infringement, ownership, inventorship or other rights with respect to any of the Intellectual Property Rights. To the knowledge of Borrower and its Subsidiaries there are no facts that could provide a reasonable basis for such a claim.

(f) None of Borrower or any of its Subsidiaries is a party to any past or pending, and neither Borrower nor its Subsidiaries has received written notice of any threat of any action, suit, or proceeding, or any investigation or claim by any Person that claims or alleges that the manufacture, use, or Commercialization of any Product, once marketed, infringes on any issued Patent or other material intellectual property rights of any other Person or constitute misappropriation of any other Person’s material trade secrets or other intellectual property rights.

(g) To the knowledge of Borrower and its Subsidiaries, no owner of any in-licensed Intellectual Property Rights is a party to any past or pending, and no owner of any in-licensed Intellectual Property Rights has received written notice of, or, to the knowledge of Borrower and its Subsidiaries, no event has occurred or circumstance exists that (with or without notice or lapse of time, or both) could reasonably be expected to give rise to or serve as a basis for any action, suit, or proceeding, or any investigation or claim by any Person that claims or alleges that the manufacture, use, or Commercialization of any Product, once marketed, infringes on any issued Patent or other intellectual property rights of any other Person or constitute misappropriation of any other Person’s trade secrets or other intellectual property rights. To the knowledge of Borrower and its Subsidiaries, the manufacture, use or Commercialization of the Product (Core) as currently conducted or proposed to be conducted, does not infringe or otherwise violate any issued Patent of any Person that the Borrower and its Subsidiaries do not have a right to use.

(h) To the knowledge of Borrower and its Subsidiaries, there is no product the manufacture or Commercialization of which infringes or, once marketed, would infringe on any issued Patents included in the Product Intellectual Property Rights that are owned by Borrower or its Subsidiaries or to the knowledge of Borrower and its Subsidiaries, that are exclusively licensed by Borrower or its Subsidiaries.

(i) To the knowledge of Borrower and its Subsidiaries, no third party is infringing or misappropriating the Intellectual Property Rights that are necessary to the conduct of Borrower's and its Subsidiaries' business as currently conducted, including the manufacture and Commercialization of the Products, except, in the case of any Product (Non-Core), where such infringement or misappropriation would not reasonably be expected to result in a Material Adverse Effect.

(j) Borrower or its Subsidiaries have applied for patent term extension in at least one U.S. patent with a claim covering the Product (Core). The Product (Core) and the U.S. patent or patents for which the application for patent term extension has been filed are eligible for patent term extension. To the knowledge of Borrower and its Subsidiaries, the application for patent term extension satisfies the requirements set forth in 35 U.S.C. § 156 and 37 C.F.R. § 1.740 in all material respects.

Section 4.24 Insurance. Each of Borrower and its Subsidiaries keeps its property adequately insured and maintains (a) insurance to such extent and against such risks, as is customary with companies in the same or similar businesses, (b) workmen's compensation insurance in the amount required by applicable law, (c) public liability insurance, which shall include product liability insurance, in the amount customary with companies in the same or similar business against claims for personal injury or death on properties owned, occupied or controlled by it, and (d) such other insurance as may be required by law or as may be required under Section 5.5. Schedule 4.24 sets forth a list of all insurance maintained by each Loan Party on the Closing Date.

Section 4.25 [Reserved].

Section 4.26 Permits, Etc.

Each Loan Party has, and is in compliance with, all permits, licenses, authorizations, approvals, entitlements and accreditations required for such Person lawfully to own, lease, manage or operate, or to acquire, each business currently owned, leased, managed or operated, or to be acquired, by such Person, that, if not obtained, could not reasonably be expected to have a Material Adverse Effect. No condition exists or event has occurred that, in itself or with the giving of notice or lapse of time or both, would result in the suspension, revocation, impairment, forfeiture or non-renewal of any such permit, license, authorization, approval, entitlement or accreditation, and there is no claim that any thereof is not in full force and effect, except, in each case, to the extent any such condition, event or claim could not reasonably be expected to have a Material Adverse Effect.

Section 4.27 Bank Accounts and Securities Accounts. Schedule 4.27 sets forth a complete and accurate list as of the Closing Date of all deposit, checking and other bank accounts, all securities and other accounts maintained with any broker dealer and all other similar accounts maintained by each Loan Party, together with a description thereof (i.e., the bank or broker dealer at which such deposit or other account is maintained and the account number and the purpose thereof).

Section 4.28 Security Interests. The Collateral Documents create in favor of Administrative Agent, for the benefit of Secured Parties, a legal, valid and enforceable security interest in the Collateral secured thereby. Upon the filing of the UCC-1 financing statements described in Section 3.1(e), the possession by Administrative Agent of any certificated Capital Stock or instrument owned by such Loan Party, the recording of the Collateral Assignments for Security referred to in each Pledge and Security Agreement in the United States Patent and Trademark Office and the United States Copyright Office, as applicable, such security interests in and Liens on the Collateral granted thereby shall be perfected, First Priority security interests (in each case, solely to the extent the making of such filings and taking of such action complies with Requirements of Law and subject to any Permitted Liens), and no further recordings or filings are or will be required in connection with the creation, perfection or enforcement of such security interests and Liens, other than (a) the filing of continuation statements in accordance with applicable law, (b) the recording of the Collateral Assignments for Security pursuant to each Pledge and Security Agreement in the United States Patent and Trademark Office and the United States Copyright Office, as applicable, with respect to after-acquired U.S. patent and trademark applications and registrations and U.S. copyrights and (c) the recordation of appropriate evidence of the security interest in the appropriate foreign registry with respect to all foreign Intellectual Property.

Section 4.29 PATRIOT ACT and FCPA. To the extent applicable, each Loan Party is in compliance with Anti-Terrorism Laws and Sanctions. Neither the Loan Parties nor any of their officers, directors, employees, agents or shareholders acting on the Loan Parties' behalf shall use the proceeds of the Loans to make any payments, directly or indirectly (including through any third party intermediary), to any Foreign Official in violation of the United States Foreign Corrupt Practices Act of 1977 (the "FCPA") or any other Anti-Corruption Laws. None of the Loan Parties nor any Affiliates of any Loan Parties, is in violation of any Anti-Terrorism Law or engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the Anti-Terrorism Laws. None of the Loan Parties, nor any Affiliates of any Loan Parties, or their respective agents acting or benefiting in any capacity in connection with the Loans or other transactions hereunder, is a Blocked Person. None of the Loan Parties, nor any of their agents acting in any capacity in connection with the Loans or other transactions contemplated hereunder (A) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (B) deals in, or otherwise engages in any transaction relating to, any property or interests in property blocked pursuant to any OFAC Sanctions Programs or Sanctions.

Section 4.30 [Reserved].

Section 4.31 Disclosure. No representation or warranty of any Loan Party contained in any Loan Document or in any other documents, certificates or written statements made or furnished to Lenders by or on behalf of Borrower or any of its Subsidiaries for use in connection with the transactions contemplated hereby, when taken as a whole, contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein not materially misleading in light of the circumstances in which the same were made. Any projections and pro forma financial information contained in such materials are based upon good faith estimates and assumptions believed by Borrower to be reasonable at the time made, it being recognized by Lenders that such projections as to future events are not to be viewed as facts and that actual results during the period or periods covered by any such projections may differ materially from the projected results. The information provided by the Loan Parties to Lenders in the Perfection Certificate (as supplemented in accordance with Section 5.1(n)) is true and correct in all material respects as of the date such Perfection Certificate was delivered.

Section 4.32 Use of Proceeds. The proceeds of the Term Loans shall be used in accordance with the requirements of Section 2.2. No portion of the proceeds of the Term Loan shall be used in any manner that causes or might cause such Credit Extension or the application of such proceeds to violate Regulation T, Regulation U or Regulation X of the Board of Governors of the Federal Reserve System or any other regulation thereof or to violate the Exchange Act.

Section 4.33 Regulatory Compliance.

(a) Each of Borrower and its Subsidiaries have all Registrations from the FDA, comparable foreign counterparts or any other Governmental Authority required to conduct their respective businesses as currently conducted, except where the failure to have all such Registrations would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. Each of such Registrations is valid and subsisting in full force and effect, except where the failure to so exist would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. To the knowledge of Borrower and its Subsidiaries, neither FDA nor any other applicable Governmental Authority is considering limiting, suspending, or revoking such Registrations or reducing the scope of the marketing authorization or materially changing the labeling of any Products under such Registrations. To the knowledge of Borrower and its Subsidiaries, there is no false or materially misleading information or material omission in any Product application or other notification, submission or report to the FDA or any other applicable Governmental Authority that was not corrected by subsequent submission, and all such applications, notifications, submissions and reports provided Borrower and its Subsidiaries were true, complete, and correct in all material respects as of the date of submission to FDA or any other applicable Governmental Authority, except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. Borrower and its Subsidiaries have not failed to fulfill and perform their obligations that are due under each such Registration, and no event has occurred or condition or state of facts exists that would constitute a breach or default under any such Registration, in each case that would reasonably be expected to cause the revocation, termination or suspension or material limitation of any such Registration, including but not limited to any form of clinical hold order, except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. To the knowledge of Borrower and its Subsidiaries, any third party that develops, researches, manufactures, commercializes, distributes, sells or markets Products pursuant to an agreement with Borrower or its Subsidiaries (a "Loan Party Partner") is in compliance with all Registrations from the FDA and any other applicable Governmental Authority insofar as they pertain to Products, and each such Loan Party Partner is, and since [***] has been, to the knowledge of Borrower and its Subsidiaries, in compliance with applicable Public Health Laws, except where the failure to so be in compliance would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. The Borrower is not required to give notice to, make any filing with, or obtain any consent from any Governmental Authority at any time prior to the Closing Date in connection with the execution and delivery of this Agreement, or the consummation of the transactions contemplated by the Loan Documents.

(b) Each of Borrower and its Subsidiaries is in compliance, and since [***], has been in compliance, with all Public Health Laws, except to the extent that any such non-compliance, individually or in the aggregate, could not reasonably be expected to result in Material Regulatory Liabilities.

(c) To the extent applicable, all products designed, developed, investigated, manufactured, prepared, assembled, packaged, tested, labeled, distributed, sold, marketed or delivered by or on behalf of Borrower or any of its Subsidiaries, that are subject to the jurisdiction of the FDA or any comparable Governmental Authority have, since [***], been and are being designed, developed, investigated, manufactured, prepared, assembled, packaged, tested, labeled, distributed, sold, marketed or delivered in compliance with the Public Health Laws, except for such noncompliance that would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. To the knowledge of Borrower and its Subsidiaries, there are no defects in the design or technology embodied in any Products that are reasonably expected to prevent the safe and effective performance of any such Product for its intended use (other than such limitations specified in the applicable package insert), except for such defects that would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities or other Liabilities. None of the Products has been the subject of any material products liability or material warranty action against Borrower or its Subsidiaries. None of the Products has been the subject of any non-legal claim for clinical trial compensation by trial participants, except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities.

(d) Neither Borrower nor any of its Subsidiaries is currently subject to any material obligation arising pursuant to a Regulatory Action and, to the knowledge of Borrower and its Subsidiaries, no such material obligation or Regulatory Action with respect to the Product has been threatened by a Governmental Authority in writing, except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities. In addition, and without limitation on the foregoing, neither Borrower nor any of its Subsidiaries has since [***], received any written notice or communication from the FDA, comparable foreign counterparts or any other Governmental Authority alleging non-compliance with any Public Health Law or comparable foreign laws, except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities.

(e) Except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities, (i) neither Borrower nor any of its Subsidiaries has since [***], received any written notice or communication from the FDA or any other Governmental Authority alleging material noncompliance with any Public Health Law, including without limitation any notice of inspectional observation, notice of adverse finding, notice of violation, warning letters, untitled letters or other notices from the FDA and (ii) to the knowledge of Borrower and its Subsidiaries, no Loan Party Partner has since [***], received any written notice or communication from the FDA or any other Governmental Authority alleging material noncompliance with any Public Health Law, including without limitation any notice of inspectional observation, notice of adverse finding, notice of violation, warning letters, untitled letters or other notices from the FDA or other Governmental Authority relating to such Loan Party Partner's work for Borrower or such Subsidiary. Except as would not reasonably be expected to, individually or in the aggregate, result in Material Regulatory Liabilities, there have been no material recalls, field notifications, field corrections, market withdrawals or replacements, detentions, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an actual or potential lack of safety, efficacy, or regulatory compliance of any Products ("Safety Notices") or clinical hold orders issued by the FDA with respect to an ongoing or anticipated clinical trial of any Product, and to the knowledge of Borrower and its Subsidiaries, there are no facts or circumstances that are reasonably likely to result in (x) a Safety Notice, (y) a change in the labeling of any Product, or (z) a termination or suspension of research, testing, manufacturing, distribution, or commercialization of any Product.

Section 4.34 Government Contracts. Except as set forth on Schedule 4.34 as of the Closing Date hereof, neither Borrower nor any of its Subsidiaries is a party to any contract or agreement with any Governmental Authority and none of Borrower's or such Subsidiary's accounts receivables or other rights to receive payment are subject to the Federal Assignment of Claims Act (31 U.S.C. Section 3727) or any similar state, county or municipal law.

Section 4.35 Health Care Laws.

(a) Each of Borrower and its Subsidiaries is operating, and since [***], has been operating in material compliance with applicable Health Care Laws. Notwithstanding the generality of the foregoing, since January 1, 2021, all of the billing and reimbursement practices of, and the claims submitted by, either directly or indirectly, each of Borrower and its Subsidiaries have been in material compliance with all applicable Health Care Laws and all written reimbursement policies of all U.S. third-party payor programs, including Federal Health Care Programs (such as the HIPAA transaction and code set standards).

(b) None of Borrower and its Subsidiaries, nor, to their knowledge, any officer, director or managing employee (as those terms are defined in 42 C.F.R. § 1001.2) thereof is a party to, or bound by, any Regulatory Action, including without limitation, any written order, individual integrity agreement, corporate integrity agreement, deferred or non-prosecution agreement or other written agreement with any Governmental Authority concerning their compliance with Health Care Laws.

(c) None of Borrower and its Subsidiaries, nor to their knowledge, any officer, director or managing employee (as those terms are defined in 42 C.F.R. § 1001.2) thereof (i) has been, since [***], charged with or convicted of any criminal offense relating to the delivery of an item or service under any Federal Health Care Program; (ii) has had, since [***], a civil monetary penalty assessed against it, him or her under Section 1128A of the Social Security Act; (iii) has been listed on the U.S. General Services Administration published list of parties excluded from federal procurement programs and non-procurement programs or (iv) to the knowledge of Borrower and its Subsidiaries, is the target or subject of any current or potential suit, claim, action, proceeding, arbitration, mediation, inquiry, subpoena or investigation relating to any of the foregoing or any Federal Health Care Program-related offense, or that would result in the imposition of material penalties or the debarment, suspension or exclusion from participation in any Federal Health Care Program. Since [***], none of Borrower and its Subsidiaries, any officer, director, managing employee or agent (as those terms are defined in 42 C.F.R. § 1001.2) thereof or, to the knowledge of Borrower and its Subsidiaries, any employee or contractor thereof, nor any Loan Party Partner, has been or is currently debarred, excluded, disqualified or suspended from participation in any Federal Health Care Program or under any FDA Laws (including 21 U.S.C. § 335a).

(d) None of Borrower and its Subsidiaries, nor any officer, director or managing employee (as those terms are defined in 42 C.F.R. § 1001.2) thereof has, since [***], violated or engaged in any activity that is in material violation of any Health Care Laws or cause for false claims liability, civil penalties or mandatory or permissive exclusion from any Federal Health Care Program.

(e) Since [***], to the knowledge of Borrower and its Subsidiaries, no person has filed or has threatened to file against Borrower or any of its Subsidiaries, an action relating to any FDA Law, Public Health Law or Health Care Law, including, without limitation, the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.) with respect to the activities of Borrower and its Subsidiaries relating to the Product.

(f) As of the Closing Date, the Borrower and its Subsidiaries do not receive any reimbursement directly from any U.S. third-party payor program, including Federal Health Care Programs, for any Product.

Section 4.36 Data Protection. Each of Borrower and its Subsidiaries is, and since [***], has been, in material compliance with all: (i) applicable Data Protection Laws; (ii) applicable industry standards with which Borrower or any Subsidiary has agreed to comply; (iii) contractual obligations to which each Loan Party is bound; and (iv) all of Borrower and each of its Subsidiaries' Privacy Policies, in each case, relating to privacy, data protection, security, consumer protection, consent, or the collection, retention, protection, use or other processing of Personal Information or other Data collected, used or maintained by Borrower or by third parties having access to the records or Data of Borrower and each of its Subsidiaries. To ensure compliance with Data Protection Laws, Borrower and its Subsidiaries have in place and materially comply with appropriate policies and procedures relating to security and protection (including appropriate organizational, technical, and physical measures) of Personal Information or other Data. Each of Borrower and its Subsidiaries has adopted, published and comply with privacy notices and policies that accurately describe the privacy practices of Borrower or any Subsidiary (as applicable), to any website, mobile application or other electronic platform and complied with those notices and policies (collectively, with each of Borrower and each of its Subsidiaries' internal privacy policies, the "Privacy Policies"). The execution, delivery and performance of this Agreement complies with all Data Protection Laws and with Borrower's and each Subsidiary's Privacy Policies in each case in all material respects. Neither Borrower nor any Subsidiary, nor to the knowledge of Borrower and its Subsidiaries, any third party processing Personal Information or other Data on behalf of Borrower or any Subsidiary, has experienced any incidents in which Personal Information or other Data in the possession, custody or control of Borrower or any of its Subsidiaries or any third party processing Personal Information or other Data on behalf of Borrower or any Subsidiary was or may have been stolen, lost or otherwise been subject to any unauthorized, unlawful, or accidental access, acquisition, use or disclosure. Neither Borrower nor any Subsidiary, nor, to the knowledge of Borrower and its Subsidiaries, any third party acting on behalf of Borrower or any Subsidiary, has received any: (i) written inquiry or complaint alleging noncompliance with Data Protection Laws; (ii) written claim for compensation for loss or unauthorized collection, processing or disclosure of Personal Information or other Data; or (iii) written request for the rectification, erasure or destruction of Personal Information or other Data that is still outstanding in violation of applicable Data Protection Laws, contractual obligations, or Privacy Policies.

ARTICLE V

AFFIRMATIVE COVENANTS

Each Loan Party covenants and agrees that, so long as any Commitment is in effect and until payment in full of all Obligations (other than any such contingent obligations or liabilities hereunder that by express terms thereof survive such payment in full of all Obligations), each Loan Party shall perform, and shall cause each of its Subsidiaries to perform, all covenants in this Article V.

Section 5.1 Financial Statements and Other Reports. Unless otherwise provided below, Borrower will deliver to Administrative Agent and Lenders:

(a) Cash Reports. Within [***] (x) after the end of each fiscal month during a Restricted Period and (y) after the end of each fiscal month of Borrower in which the ending Cash and Cash Equivalent balances of the Loan Parties is less than \$[***], a report of the current Cash and Cash Equivalent balances of the Borrower and its Subsidiaries, which report shall identify Qualified Cash and other unrestricted and restricted Cash and Cash Equivalents.

(b) Quarterly Financial Statements. Within 45 days after the end of each Fiscal Quarter of each Fiscal Year (excluding the fourth Fiscal Quarter), the consolidated balance sheets of Borrower and its Subsidiaries as at the end of such Fiscal Quarter and the related consolidated statements of income, stockholders' equity and cash flows of Borrower and its Subsidiaries for such Fiscal Quarter and for the period from the beginning of the then current Fiscal Year to the end of such Fiscal Quarter, setting forth in each case in comparative form the corresponding figures for the corresponding periods of the previous Fiscal Year, all in reasonable detail, together with a Financial Officer Certification with respect thereto;

(c) Annual Financial Statements. Within 90 days after the end of each Fiscal Year, (i) the consolidated balance sheets of Borrower and its Subsidiaries as at the end of such Fiscal Year and the related consolidated statements of income, stockholders' equity and cash flows of Borrower and its Subsidiaries for such Fiscal Year, setting forth in each case in comparative form the corresponding figures for the previous Fiscal Year, in reasonable detail, together with a Financial Officer Certification with respect thereto; and (ii) with respect to such consolidated financial statements a report thereon of KPMG LLP or other independent certified public accountants of recognized national standing selected by Borrower or that is otherwise reasonably satisfactory to Administrative Agent (which report shall be unqualified as to going concern and scope of audit (other than with respect to or resulting from an upcoming maturity of Indebtedness under this Agreement), shall not contain any going concern emphasis of matter and shall state that such consolidated financial statements fairly present, in all material respects, the consolidated financial position of Borrower and its Subsidiaries as at the dates indicated and the results of their operations and their cash flows for the periods indicated in conformity with GAAP);

(d) Compliance Certificate. Together with each delivery of financial statements of Borrower and its Subsidiaries pursuant to Section 5.1(b) or Section 5.1(c), a duly executed and completed Compliance Certificate attaching a report of the current Cash and Cash Equivalent balances of the Borrower and its Subsidiaries, which report shall identify Qualified Cash and other unrestricted and restricted Cash and Cash Equivalents;

(e) Royalty Reports; Notice of Disputes. Promptly (but in any event within [***]) after receipt by Borrower or any of its Subsidiaries, (i) a copy of any royalty reports or similar reports outlining fees to be paid or payable with respect the Commercialization of any Product (Core) in any Material Jurisdiction from any third party Licensee or (ii) any notices of any material third party disputes with respect to a Product (Core) or any Product (Core) Intellectual Property Rights, in each case, in any Material Jurisdiction or any Specified Jurisdiction.

(f) [Reserved];

(g) Notice of Default. Promptly (but in any event within [***]) upon any officer of Borrower obtaining knowledge (i) of any condition or event that constitutes a Default or an Event of Default; (ii) that any Person has given any notice to Borrower or any of its Subsidiaries or taken any other action with respect to any event or condition set forth in Section 8.1(b); or (iii) of the occurrence of any event or change that has caused or evidences or results in, in any case or in the aggregate, a Material Adverse Effect or Material Regulatory Liabilities, a certificate of its Authorized Officers specifying the nature and period of existence of such condition, event or change, or specifying the notice given and action taken by any such Person and the nature of such claimed Event of Default, Default, default, event or condition, and what action Borrower has taken, is taking and proposes to take with respect thereto;

(h) Notice of Litigation. Promptly (but in any event within [***]) upon any officer of Borrower obtaining knowledge of (i) the institution of any Adverse Proceeding or (ii) any material development in any Adverse Proceeding that, in the case of either clause (i) or (ii), that relates to the Products, the Product Intellectual Property or the Material Contracts, that seeks to enjoin or otherwise prevent the consummation of, or to recover any damages or obtain relief as a result of, the transactions contemplated hereby or that would reasonably be expected to result in Material Regulatory Liabilities or a Material Adverse Effect, written notice thereof together with such other information as may be reasonably available to Borrower to enable Lenders and their counsel to evaluate such matters;

(i) ERISA. Promptly (but in any event within [***]) upon becoming aware of the occurrence of or forthcoming occurrence of any ERISA Event that would reasonably be expected to result in a material Liability to a Loan Party or the imposition of a Lien, a written notice specifying the nature thereof, what action a Loan Party or any ERISA Affiliate has taken, is taking or proposes to take with respect thereto and, when known, any action taken or threatened by the Internal Revenue Service, the Department of Labor or the PBGC with respect thereto;

(j) [Reserved];

(k) Regulatory and Product Notices. Each Loan Party shall promptly (but in any event within [***]) after the receipt or occurrence thereof notify Administrative Agent of:

(i) any written notice received by Borrower or its Subsidiaries alleging potential or actual material violations of any Public Health Law or Health Care Law, in each case, in any Material Jurisdiction or any Specified Jurisdiction by Borrower or its Subsidiaries,

(ii) any written notice received by Borrower or its Subsidiaries that the FDA (or international equivalent) or other Governmental Authority in any Material Jurisdiction or any Specified Jurisdiction is limiting, suspending or revoking any Registration (including, but not limited to, by the issuance of a clinical hold),

(iii) any written notice received by Borrower or its Subsidiaries that Borrower or its Subsidiaries has become subject to any Regulatory Action (other than any routine inspection or investigation in the ordinary course of business) in any Material Jurisdiction or any Specified Jurisdiction,

(iv) the exclusion or debarment from any Federal Health Care Program or debarment or disqualification by FDA (or international equivalent) of Borrower or its Subsidiaries or its or any officer, director, managing employee or agent (as those terms are defined in 42 C.F.R. § 1001.2) thereof or any employee or contractor thereof,

(v) any written notice received by Borrower or its Subsidiaries that a Borrower or any Subsidiary, or any of their licensees or sublicensees (including licensees or sublicensees under the Product Agreements related to Product Intellectual Property Rights or Material Contracts), is being investigated or is the subject of any allegation of potential or actual violations of any Public Health Law or Health Care Laws, in each case, in any Material Jurisdiction or any Specified Jurisdiction,

(vi) any written notice received by Borrower or its Subsidiaries that any product of Borrower or its Subsidiaries has been seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing, or the commencement of any proceedings in any Material Jurisdiction or Specified Jurisdiction seeking the withdrawal, recall, suspension, import detention, or seizure of any Product are pending or threatened in writing against Borrower or its Subsidiaries, or

(vii) narrowing of the scope of marketing authorization or the labeling of the products of Borrower and its Subsidiaries under any Registration, in each case, in any Material Jurisdiction or any Specified Jurisdiction,

except, in each case of (i) through (iii) and (v) through (vii) above, where such action would not reasonably be expected to have, either individually or in the aggregate, any Material Regulatory Liabilities; provided, however, that with respect to any occurrence in clauses (i) through (vii) above that would, with notice or the passage of time, or both, lead to a Default or an Event of Default under Section 8.1(o) of this Agreement, each Loan Party shall promptly (but in any event within [***] of Administrative Agent's request) provide to Administrative Agent copies of all communications with FDA and all other documentation and information in such Loan Party's possession, custody or control reasonably requested by Administrative Agent relating to such notice or change and the events that led up to it (subject to suitable confidentiality restrictions);

(l) Notice Regarding Material Contracts. Promptly (but in any event within [**]) (A) after a Loan Party or a Subsidiary of a Loan Party receives any written notice of default or event of default under any Material Contract, or (B) after Loan Party or a Subsidiary of a Loan Party receives or otherwise becomes aware of any dispute, litigation, purchase price adjustment (other than in accordance with the terms of such Material Contract), indemnity claim, exercise of rights of set-off or deduction (including any of the foregoing threatened in writing) under or with respect any Material Contract in each case, reasonably expected to be in excess of \$[***], furnish a written statement describing such event, with copies of such notices or new contracts together with all pertinent detail and information relating thereto in such Loan Party or Subsidiary of Loan Party's possession, custody or control and to the extent allowed to be delivered pursuant to its terms, delivered to Administrative Agent, and an explanation of any actions being taken with respect thereto. Borrower shall promptly provide Administrative Agent with written notice upon becoming aware of a counterparty's material breach of its obligations under any Material Contract. Concurrently with the delivery of a Compliance Certificate in accordance with Section 5.1(d), and promptly following Administrative Agent's reasonable request from time to time, Borrower shall promptly provide to Administrative Agent copies of any and all new Material Contracts not yet provided to the Administrative Agent;

(m) Information Regarding Collateral. Borrower will furnish to Administrative Agent prior written notice of any change (a) in any Loan Party's legal name, (b) in any Loan Party's jurisdiction of organization or (c) in any Loan Party's U.S. federal or other taxpayer identification number (if any). Borrower agrees not to effect or permit any change referred to in the preceding sentence unless all filings have been made under the UCC or otherwise that are required in order for Administrative Agent to continue at all times following such change to have a valid, legal and perfected security interest in all the Collateral and for the Collateral at all times following such change to have a valid, legal and perfected security interest as contemplated in the Collateral Documents. Borrower also agrees promptly to notify Administrative Agent if any material portion of the Collateral is damaged or destroyed;

(n) Annual Collateral Verification. Each year, at the time of delivery of annual financial statements with respect to the preceding Fiscal Year pursuant to Section 5.1(c), Borrower shall deliver to Administrative Agent an updated Perfection Certificate (or confirming that there has been no change in such information since the previous Perfection Certificate);

(o) Product. Promptly, but in any event within [***] after the receipt by Borrower or any of its Subsidiaries or occurrence thereof, as applicable, notify Administrative Agent of:

(i) granting of any licenses or sublicenses under any Permitted Product Agreement;

(ii) amending an existing, or entering into any new Permitted Product Agreement;

(iii) any material written communications received from the FDA (or international equivalent) or other Governmental Authority in any Material Jurisdiction or any Specified Jurisdiction that would reasonably be expected to result in a Material Adverse Effect; and

(iv) copies of all royalty reports relating to any Product (x) provided to a third party by Borrower or its Subsidiaries, or (y) received by Borrower or its Subsidiaries from a third party, in the case of (x) and (y), to the extent not prohibited by obligations of confidentiality owed to third parties;

(p) Notices relating to Intellectual Property. Promptly (but in any event within [***]), deliver written notice of material infringements of any material Intellectual Property Rights owned or licensed by such Loan Party or any of its Subsidiaries that are known to Borrower;

(q) Regulatory Documentation. To the extent permitted and within the control of Borrower under each Product Agreement, Borrower shall be responsible for, and shall maintain, with respect to each Product, all submissions to Governmental Authorities in all Material Jurisdiction and Specified Jurisdictions relating to the Products, including clinical studies, tests and biostudies, including all Product non-disclosure agreements, and the drug master files, as well as all correspondence with Governmental Authorities in all Material Jurisdictions and Specified Jurisdictions with respect thereto (including Registrations and licenses and regulatory drug lists, and any amendments or supplements thereto). Concurrently with the delivery of a Compliance Certificate following the end of each Fiscal Quarter in accordance with Section 5.1(d) and promptly following Administrative Agent's reasonable request from time to time, Borrower shall promptly provide to Administrative Agent copies of any and all material regulatory filings submitted to any such Governmental Authorities with respect to the Products to the extent such disclosure is not prohibited by obligations of confidentiality owed to third parties;

(r) Prosecution, Maintenance, Defense and Enforcement of Product Patents. To the extent permitted and within the control of Borrower under each Product Agreement, Borrower shall take all commercially reasonable steps to prosecute, maintain, defend and enforce the Product Patents, including by timely paying fees and filing responses with the United States Patent and Trademark Office or any applicable foreign counterpart. To the extent permitted under any obligations of confidentiality owed to third parties, Borrower shall provide prompt written notice to Administrative Agent of any material occurrences with respect to any Product Patents of which Borrower gains knowledge, including claims of invalidity or unenforceability made by a third party, or infringement of Product Patents by a third party. To the extent permitted under any obligations of confidentiality owed to third parties, upon Administrative Agent's request from time to time, Borrower shall promptly provide Administrative Agent with complete and correct copies of (i) a list of Purple Book Patents or listing of Product Patents provided to a biosimilar applicant, and (ii) any pleadings, briefs, declarations, correspondence and other documents relating to any Dispute involving any such Purple Book Patents that are controlled or received by Borrower or any of its Subsidiaries;

(s) Infringement of Third Party Patents. Borrower shall provide prompt written notice to Administrative Agent of any claim, notice, or allegation received by Borrower that Commercialization of the Product (Core) infringes a third party patent. To the extent permitted under any obligations of confidentiality owed to third parties, upon Administrative Agent's request from time to time, Borrower shall promptly provide Administrative Agent with complete and correct copies of (i) the third party patent and (ii) any pleadings, briefs, declarations, correspondence and other documents relating to any Dispute involving any such third party patents that are controlled or received by Borrower;

(t) Patent Term Extension. Borrower shall take all steps to obtain patent term extension on a Product Patent in the United States, including timely responding to requests from the United States Patent and Trademark Office and timely electing the patent to which patent term extension will be applied;

(u) [Reserved];

(v) Projections. Within [***] of approval by Borrower's Board of Directors, and in any event within [***] after the end of each fiscal year, any financial, business and any other projections of Borrower and its Subsidiaries (and upon the reasonable request of Administrative Agent, budgets, operating plans and other financial information) that, in each case, have been approved by Borrower's Board of Directors; and

(w) Other Information. (i) Promptly upon their becoming available and in any event within [***] of Borrower's receipt thereof, copies of all amendments, waivers, consents, notices of defaults and reservations of rights with respect to and received by Borrower or its Subsidiaries from any holder of its Indebtedness having a principal amount greater \$[***], (ii) promptly after submission to any Governmental Authority in any Material Jurisdiction or any Specified Jurisdiction, all material documents and information furnished to such Governmental Authority in connection with any investigation of any Loan Party (other than a routine inquiry), and (iii) such other information and data with respect to Borrower or any of its Subsidiaries as from time to time may be reasonably requested by Administrative Agent.

Notwithstanding the foregoing, the obligations in paragraphs (b) and (c) of this Section 5.1 may be satisfied with respect to financial information of Borrower and its Subsidiaries by furnishing Borrower's Form 10-K or 10-Q, as applicable, filed with the SEC. Further, notwithstanding anything to the contrary in this Section 5.1, neither the Borrower nor any of its Subsidiaries will be required to disclose or permit the inspection or discussion of, any document, information or other matter (i) in respect of which disclosure (or their respective representatives or contractors) is prohibited by Requirements of Law or any binding agreement or (ii) that is subject to attorney client or similar privilege or constitutes attorney work product, in each case based on the advice of counsel to Borrower.

Section 5.2 Existence. Except as otherwise permitted under Section 6.9, each Loan Party will, and will cause each of Borrower's Subsidiaries to, at all times preserve and keep in full force and effect its existence and all rights and Governmental Authorizations, qualifications, franchises, licenses and permits material to its business and to conduct its business in each jurisdiction in which its business is conducted; provided, no Loan Party or any of Borrower's Subsidiaries shall be required to preserve any such existence, right or Governmental Authorizations, qualifications, franchise, licenses and permits if such Person's Board of Directors (or similar governing body) shall determine that the preservation thereof is no longer desirable in the conduct of the business of such Person, and that the loss thereof is not disadvantageous in any material respect to such Person or to Lenders.

Section 5.3 Payment of Taxes and Claims. Each Loan Party will, and will cause each of Borrower's Subsidiaries to, file all income and other material Tax returns required to be filed by or with respect to Borrower or any of its Subsidiaries and timely pay all income or other material Taxes imposed upon or with respect to it (including in its capacity as a withholding agent) or any of its properties, assets, income, businesses or franchises before any penalty or fine accrues thereon, and all claims (including claims for labor, services, materials and supplies) for sums that have become due and payable and that by law have or may become a Lien upon any of its properties or assets, prior to the time when any penalty or fine shall be incurred with respect thereto; provided, no such Tax or claim need be paid if it is being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as (a) adequate reserve or other appropriate provision, as shall be required in conformity with GAAP shall have been made therefor, and (b) in the case of a Tax or claim that has or may become a Lien against any of the Collateral, such contest proceedings conclusively operate to stay imposition of any penalty, fine or Lien resulting from the non-payment thereof. No Loan Party will, nor will it permit any of the Borrower's Subsidiaries to, file or consent to the filing of any consolidated income tax return with any Person (other than the Borrower or its Subsidiaries).

Section 5.4 Maintenance of Properties. Each Loan Party will, and will cause each of Borrower's Subsidiaries to (a) maintain or cause to be maintained in good repair, working order and condition, ordinary wear and tear excepted, all properties used or useful in the business of Borrower and its Subsidiaries and from time to time will make or cause to be made all appropriate repairs, renewals and replacements thereof, except to the extent any such failure to maintain could not reasonably be expected to have a Material Adverse Effect, and (b) comply at all times with the provisions of all material leases to which it is a party as lessee or under which it occupies property, so as to prevent any loss or forfeiture thereof or thereunder, except to the extent any such failure to comply could not reasonably be expected to have a Material Adverse Effect.

Section 5.5 Insurance.

(a) The Loan Parties will maintain or cause to be maintained, with financially sound and reputable insurers, (i) business interruption insurance, and (ii) casualty insurance, such public liability insurance, third party property damage insurance or such other insurance with respect to liabilities, losses or damage in respect of the assets, properties and businesses of the Loan Parties as may customarily be carried or maintained under similar circumstances by Persons of established reputation engaged in similar businesses, in each case in such amounts (giving effect to self-insurance), with such deductibles, covering such risks and otherwise on such terms and conditions as shall be customary for such Persons. Each such policy of insurance shall (1) name Administrative Agent, on behalf of Lenders as an additional insured thereunder as its interests may appear, and (2) in the case of each casualty insurance policy, contain a loss payable clause or endorsement, satisfactory in form and substance to Administrative Agent, that names Administrative Agent, on behalf of Secured Parties as the loss payee thereunder. If any Loan Party or any of its Subsidiaries fails to maintain such insurance, Administrative Agent may, upon [***] prior written notice to Borrower, arrange for such insurance, but at Borrower's expense and without any responsibility on Administrative Agent's part for obtaining the insurance, the solvency of the insurance companies, the adequacy of the coverage, or the collection of claims. Upon the occurrence and during the continuance of an Event of Default, following notice to the Borrower, Administrative Agent shall have the sole right, in the name of the Lenders, any Loan Party and its Subsidiaries, to file claims under any insurance policies, to receive, receipt and give acquittance for any payments that may be payable thereunder, and to execute any and all endorsements, receipts, releases, assignments, reassignments or other documents that may be necessary to effect the collection, compromise or settlement of any claims under any such insurance policies.

(b) Each of the insurance policies required to be maintained under this Section 5.5 shall provide for at least thirty (30) days' prior written notice to Administrative Agent of the cancellation or substantial modification thereof. Receipt of such notice shall entitle Administrative Agent (but Administrative Agent shall not be obligated), upon 10 days prior written notice to Loan Parties, to renew any such policies, cause the coverages and amounts thereof to be maintained at levels required pursuant to this Section 5.5 or otherwise to obtain similar insurance (including with respect to coverage types, limits and premiums) in place of such policies, in each case at the expense of the Loan Parties.

Section 5.6 Books and Records; Inspections. Each Loan Party will, and will cause each of Borrower's Subsidiaries to, (a) maintain at all times at the chief executive office of Borrower copies of all material books and records of Borrower and its Subsidiaries, (b) keep adequate books of record and account in which full, true and correct entries in all material respects are made of all dealings and transactions in relation to its business and activities, and (c) permit any representatives designated by Administrative Agent (including employees of Administrative Agent, any Lender or any consultants, auditors, accountants, lawyers and appraisers retained by Administrative Agent) to visit any of the properties of any Loan Party and any of Borrower's Subsidiaries to inspect, copy and take extracts from its and their financial and accounting records, and to discuss its and their affairs, finances and accounts with its and their officers and independent accountants and auditors, all upon reasonable notice and at such reasonable times during normal business hours (so long as no Default or Event of Default has occurred and is continuing) and as often as may reasonably be requested; provided that, absent the occurrence and continuance of an Event of Default, Administrative Agent and Lenders shall not exercise such rights more often than [***] during any Fiscal Year. The Loan Parties agree to pay the reasonable and documented out-of-pocket costs and expenses incurred by the examiner in connection therewith.

Section 5.7 Lenders Calls. Borrower shall, upon the request by Administrative Agent, cause its chief financial officer or other Authorized Officers reasonably requested by Administrative Agent to participate in a conference call with Administrative Agent and all Lenders who choose to participate in such conference call, during which conference call the chief financial officer or such Authorized Officer (as applicable) shall review the financial condition of Borrower and its Subsidiaries and such other matters as Administrative Agent or any Lender may reasonably request; provided that such calls shall not occur more than [***] per calendar quarter.

Section 5.8 Compliance with Laws.

(a) Each Loan Party will comply, and shall cause each of Borrower's Subsidiaries and all other Persons, if any, on or occupying any real property, to comply, with the requirements of all applicable laws, rules, regulations and orders of any Governmental Authority (including all Environmental Laws, Data Protection Laws, Public Health Laws and Health Care Laws), non-compliance with which would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(b) Without limiting the generality of the foregoing, each Loan Party shall, and shall cause each of Borrower's Subsidiaries to, comply with all FDA Laws and Public Health Laws, and with all Data Protection Laws and applicable Health Care Laws, except where the failure to comply would not reasonably be expected to result, either individually or in the aggregate, in Material Regulatory Liabilities. All products developed, manufactured, tested, investigated, distributed or marketed by or on behalf of the Loan Parties and Borrower's Subsidiaries that are subject to the jurisdiction of the FDA or any comparable Governmental Authority have been and shall be developed, tested, manufactured, investigated, distributed, sold and marketed in compliance with the FDA Laws and any other Requirement of Law, including, without limitation, good manufacturing practices, good tissue practices, labeling, advertising, record-keeping, and adverse event reporting, except where the failure to comply would not reasonably be expected to result, either individually or in the aggregate, in Material Regulatory Liabilities.

Section 5.9 Environmental.

(a) Each Loan Party shall (i) keep its real property free of any Environmental Liens; (ii) maintain and comply in all material respects with all Governmental Authorizations required under applicable Environmental Laws, except as any such failure could not reasonably be expected to result in a Material Adverse Effect; (iii) take all steps to prevent any Release of Hazardous Materials from any property owned or operated by any Loan Party, except as any such failure could not reasonably be expected to result in a Material Adverse Effect; and (iv) ensure that there are no Hazardous Materials on, at or migrating from any property owned or operated by any Loan Party, except as any such failure could not reasonably be expected to result in a Material Adverse Effect.

(b) The Loan Parties shall promptly (but in any event within [**]) (i) notify Administrative Agent in writing (A) of any material Environmental Claims asserted in writing against or material Environmental Liabilities and Costs of any Loan Party, and (B) of any written notice of Environmental Lien filed against its real property, and (ii) provide such other documents and information as reasonably requested by Administrative Agent in relation to any matter pursuant to this Section 5.9(b).

Section 5.10 Subsidiaries. In the event that (x) any Subsidiary of a Loan Party ceases to be an Excluded Subsidiary or (y) any Person becomes a Subsidiary of a Loan Party and such Person is not an Excluded Subsidiary, Borrower, in each case, shall (a) within [**] (or such longer period as Administrative Agent may agree in writing) of such Person becoming a Subsidiary or ceasing to be an Excluded Subsidiary cause such Subsidiary to become a Guarantor hereunder and a Grantor under the Pledge and Security Agreement by executing and delivering to Administrative Agent a Counterpart Agreement, and (b) take all such actions and execute and deliver, or cause to be executed and delivered, all such documents, instruments, agreements, and certificates as are similar to those described in Sections 3.1(b), 3.1(f), and 3.1(i). With respect to each such Subsidiary, Borrower shall promptly send to Administrative Agent written notice setting forth with respect to such Person (i) the date on which such Person became a Subsidiary of Borrower or ceased to be an Excluded Subsidiary, which such notice, in the case of any Subsidiary that has ceased to be an Excluded Subsidiary, shall be provided within [**] of delivery of the financial statements for the Fiscal Quarter in which such Subsidiary ceased to be an Excluded Subsidiary, and (ii) all of the data required to be set forth in Schedules 4.1 and 4.2 with respect to all Subsidiaries of Borrower; provided, such written notice shall be deemed to supplement Schedules 4.1 and 4.2 for all purposes hereof. In addition, at the election of Borrower, any Excluded Subsidiary of Borrower may become a Guarantor hereunder, at which time such Subsidiary shall cease to be an Excluded Subsidiary.

Section 5.11 Real Estate Assets. In the event that any Loan Party acquires fee title to Material Real Property during the term of this Loan, Borrower shall send to Administrative Agent a written notice of the occurrence of any such event promptly upon the occurrence of same. Within [***] days after the acquisition of any such Material Real Property (or such later time as agreed to by Administrative Agent in its sole discretion), such Loan Party shall deliver to Administrative Agent: (a) a fully executed and notarized Mortgage, in proper form for creating a valid and enforceable lien on the Real Property described therein once recorded in the appropriate real estate records and in proper form for recording in such real estate records; (b) an opinion of counsel in the jurisdiction in which such Real Property is located with respect to the enforceability of such Mortgage and such other matters as Administrative Agent may reasonably request, in each case in form and substance reasonably satisfactory to Administrative Agent; (c)(i) an ALTA extended mortgagee title insurance policy or an unconditional commitment therefor with respect to such Mortgage (each, a “Title Policy”) from a title company reasonably satisfactory to Administrative Agent (the “Title Company”), in an amount not less than the fair market value of such Real Estate Asset, together with a title report issued by the Title Company with respect thereto, dated not more than [***] prior to the date such Real Property was acquired and copies of all recorded documents listed as exceptions to title or otherwise referred to therein, which Title Policy shall be effective as of the date of the Mortgage and otherwise be in form and substance reasonably satisfactory to Administrative Agent and (ii) evidence satisfactory to Administrative Agent that such Loan Party has paid to or deposited with the Title Company all expenses and premiums of the Title Company and all other sums required in connection with the issuance of such Title Policy and all recording and stamp taxes (including mortgage recording and intangible taxes) payable in connection with recording the Mortgage for such Real Property in the appropriate real estate records; (d) to the extent required by law, evidence of flood insurance with respect to such Real Property in compliance with any applicable regulations of the Board of Governors of the Federal Reserve System, and in form and substance reasonably satisfactory to Administrative Agent; and (e) an ALTA/NSPS survey of such Real Property in form sufficient to permit the Title Company to issue the Title Policy in the form required by Administrative Agent and otherwise in form and substance satisfactory to Administrative Agent, which shall be either (1) certified to Administrative Agent and dated not more than [***] prior to the date such Real Property was acquired, or (2) accompanied by a survey or “no change” affidavit executed by the owner of such Real Property and acceptable to the Title Company to issue the Title Policy in the form required by Administrative Agent, as applicable. In addition to the foregoing, Borrower shall, at the request of Required Lenders, deliver to Administrative Agent an appraisal of such Material Real Property to verify the amount of the Mortgage or Title Policy, but only if required by applicable law or regulation.

Section 5.12 Further Assurances. At any time or from time to time upon the reasonable request of Administrative Agent, each Loan Party will, at its expense, promptly execute, acknowledge and deliver such further documents and do such other acts and things as Administrative Agent may reasonably request in order to effect fully the purposes of the Loan Documents, including providing Lenders with any information reasonably requested pursuant to Section 10.23. In furtherance and not in limitation of the foregoing, each Loan Party shall take such actions as Administrative Agent may reasonably request from time to time to ensure that the Obligations are guaranteed by the Guarantors and are secured by the Collateral.

Section 5.13 Control Agreements. Each of Borrower and each Guarantor shall hold all of its cash and Cash Equivalents in a Deposit Account or Securities Account (other than Excluded Accounts) subject to a Control Agreement within [***] days after the Closing Date (or such later date as agreed by the Administrative Agent in its sole discretion) or the opening or acquisition thereof, as applicable. All such Control Agreements governed under the laws of a state or territory of the United States shall provide for “springing” cash dominion with respect to each such account, including each disbursement account. With respect to each Control Agreement, the Administrative Agent will not deliver to the relevant depository institution a notice or other instruction that provides for exclusive control over such account by the Administrative Agent unless an Event of Default has occurred and is continuing.

Section 5.14 Post-Closing Matters. Borrower shall, and shall cause each of the Loan Parties to, satisfy the requirements set forth on Schedule 5.14 on or before the post-closing date specified for such requirement or such later date to be determined by Administrative Agent in its sole discretion.

ARTICLE VI

NEGATIVE COVENANTS

Each Loan Party covenants and agrees that, so long as any Commitment is in effect and until payment in full of all Obligations (other than any such contingent obligations or liabilities hereunder that by express terms thereof survive such payment in full of all Obligations), such Loan Party shall perform, and shall cause each of its Subsidiaries to perform, all covenants in this Article VI.

Section 6.1 Indebtedness. No Loan Party shall, nor shall it permit any of its Subsidiaries to, directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to any Indebtedness, except Permitted Indebtedness.

Section 6.2 Liens. No Loan Party shall, nor shall it permit any of its Subsidiaries to, directly or indirectly, create, incur, assume or permit to exist any Lien on or with respect to any property or asset of any kind (including any document or instrument in respect of goods or accounts receivable) of Borrower or any of its Subsidiaries, whether now owned or hereafter acquired, or any income or profits therefrom, except Permitted Liens.

Section 6.3 Material Contracts. Borrower and its Subsidiaries shall not breach any Material Contract, or otherwise default under any Material Contract, in each case, in such a manner as could reasonably be expected to give rise to a termination right of any other party to such Material Contract. Borrower and its Subsidiaries shall not amend or permit the amendment of any provision of any Material Contract the result of which would be materially adverse to the interests of the Administrative Agent and the Lenders (in their respective capacities as such) or which would adversely affect in any material respect any of Borrower's or its Subsidiary's rights with respect to any Product (Core). For the avoidance of doubt, [***].

Section 6.4 No Further Negative Pledges. Except with respect to (a) specific property encumbered to secure payment of particular Indebtedness or to be sold pursuant to an executed agreement with respect to an Asset Sale permitted under Section 6.9, (b) [reserved], (c) restrictions by reason of customary provisions restricting assignments, subletting or other transfers contained in leases, licenses and similar agreements entered into in the ordinary course of business (provided that such restrictions are limited to the property or assets secured by such Liens or the property or assets subject to such leases, licenses or similar agreements, as the case may be), (d) [reserved], (e) restrictions under any agreement or other instrument of a Person acquired by or merged, amalgamated or consolidated with or into Loan Party that was in existence at the time of such acquisition (or at the time it merges with or into any Loan Party in connection with the acquisition of assets from such Person (but, in each case, not created in contemplation thereof)), which encumbrance or restriction is not applicable to any Person, or the properties or assets of any Person, other than the Person, or the property or assets of the Person, so acquired or designation, (f) restrictions on cash or other deposits or net worth imposed by customers under commercial contracts entered into in the ordinary course of business, (g) encumbrances or restrictions in connection with any Permitted Product Transaction that, in the good faith determination of the Borrower, are reasonably necessary or advisable in connection with such Permitted Product Transaction, (h) customary provisions in joint venture agreements or arrangements and other similar agreements or arrangements relating solely to the applicable joint venture, (i) any encumbrance or restriction contained in secured Indebtedness otherwise permitted to be incurred hereunder to the extent limiting the right of the debtor to dispose of the assets securing such Indebtedness and (j) any encumbrances or restrictions of the type referred to in the immediately preceding clauses (a) through (i) above imposed by any amendments, modifications, restatements, renewals, increases, supplements, refundings, replacements or refinancings of the contracts, instruments or obligations referred to such immediately preceding clauses (a) through (i) above; *provided* that such encumbrances and restrictions contained in any such amendment, modification, restatement, renewal, increase, supplement, refunding, replacement or refinancing are, in the good faith judgment of the Borrower, not materially more restrictive, taken as a whole, than the encumbrances and restrictions prior to such amendment, modification, restatement, renewal, increase, supplement, refunding, replacement or refinancing, no Loan Party nor any of Borrower's Subsidiaries shall enter into any agreement prohibiting the creation or assumption of any Lien upon any of its properties or assets, whether now owned or hereafter acquired.

Section 6.5 Restricted Junior Payments. No Loan Party shall, nor shall it permit any of its Subsidiaries through any manner or means or through any other Person to, directly or indirectly, declare, order, pay or make any sum for any Restricted Junior Payment, in each case, except for:

(a) the payment of dividends to Borrower's equityholders in the form of Common Stock;

(b) (i) the issuance of Capital Stock of Borrower upon the exercise of any warrants, options or rights to acquire such Capital Stock, including upon conversion of any Indebtedness that is convertible into or exchangeable for Capital Stock of Borrower, and (y) cash payments in lieu of issuing fractional shares in connection with the exercise of warrants, options or other securities convertible or exchangeable into Capital Stock of Borrower;

(c) the payment of dividends or other Restricted Junior Payments by a Subsidiary of Borrower to Borrower or such Subsidiary's direct parent company;

(d) the repurchase, retirement or other acquisition or retirement for value of Borrower's Capital Stock held by any future, present or former employee, director, manager, officer or consultant (or any Affiliates, spouses, former spouses, other immediate family members, successors, executors, administrators, heirs, legatees or distributees of any of the foregoing) of Borrower or any of its Subsidiaries pursuant to any employee, management, director or manager equity plan, employee, management, director or manager stock option plan or any other employee, management, director or manager benefit plan or any agreement (including any stock subscription or shareholder agreement) with any employee, director, manager, officer or consultant of Borrower or any Subsidiary; provided that the aggregate amounts of all such payments made pursuant to this clause (d) shall not exceed \$[***] in any fiscal year; and

(e) [***];

(f) any payment on subordinated Indebtedness in accordance with the subordination agreement governing such Indebtedness;

(g) [reserved]; and

(h) the Loan Parties may purchase, redeem, retire or otherwise acquire for value Capital Stock (and any related stock appreciation rights, plans, equity incentive or achievement plans or any similar plans) of a Person being acquired in any Permitted Acquisition or other Investment permitted by Section 6.7 in connection with such Permitted Acquisition or other Investment; provided that such purchase, redemption, retirement or acquisition shall be a part of the consideration or purchase price paid for such Permitted Acquisition (i.e. subject to any applicable caps with respect to the purchase price of such Permitted Acquisition).

Notwithstanding anything to the contrary contained herein, at no time during a Restricted Period shall any Restricted Junior Payment otherwise permitted under the foregoing clauses (d), (e), (f) or (h) be made.

Section 6.6 Restrictions on Subsidiary Distributions. Except as provided herein, no Loan Party shall, nor shall it permit any of its Subsidiaries to, create or otherwise cause or suffer to exist or become effective any consensual encumbrance or restriction of any kind on the ability of any Subsidiary of Borrower to (a) pay dividends or make any other distributions on any of such Subsidiary's Capital Stock owned by Borrower or any other Subsidiary of Borrower, (b) repay or prepay any Indebtedness owed by such Subsidiary to Borrower or any other Subsidiary of Borrower, (c) make loans or advances to Borrower or any other Subsidiary of Borrower, or (d) transfer any of its property or assets to Borrower or any other Subsidiary of Borrower other than restrictions (i) in agreements evidencing purchase money Indebtedness permitted by clause (h) of the definition of Permitted Indebtedness that impose restrictions on the property so acquired, (ii) by reason of customary provisions restricting assignments, subletting or other transfers contained in leases, licenses, joint venture agreements and similar agreements entered into in the ordinary course of business, and (iii) that are or were created by virtue of any transfer of, agreement to transfer or option or right with respect to any property, assets or Capital Stock not otherwise prohibited under this Agreement. No Loan Party shall, nor shall it permit its Subsidiaries to, enter into any Contractual Obligations that would prohibit a Subsidiary of Borrower from being a Loan Party (other than Subsidiaries that are Excluded Subsidiaries, other than by virtue of clause (c) or (f) of the definition thereof).

Section 6.7 Investments. No Loan Party shall, nor shall it permit any of its Subsidiaries to, directly or indirectly, make or own any Investment in any Person, including without limitation, any Joint Venture, except Permitted Investments. Notwithstanding the foregoing, in no event shall any Loan Party make any Investment that results in the making of any Restricted Junior Payment not otherwise permitted under the terms of Section 6.5.

Section 6.8 Minimum Qualified Cash. The Loan Parties shall not permit Qualified Cash at any time to be less than \$[***] and, at any time during a Restricted Period, to be less than \$[***].

Section 6.9 Fundamental Changes; Disposition of Assets

No Loan Party shall, nor shall it permit any of its Subsidiaries to:

(a) enter into any merger or consolidation, or liquidate, wind up or dissolve itself (or suffer any liquidation or dissolution), including by means of a "plan of division" under the Delaware Limited Liability Company Act or any comparable transaction under any similar law, except:

(i) (x) any Subsidiary of Borrower that is a Loan Party may be merged with or into Borrower or any Guarantor Subsidiary, or be liquidated, wound up or dissolved, or all or any part of its business, property or assets may be conveyed, sold, leased, transferred or otherwise disposed of, in one transaction or a series of transactions, to Borrower or any Guarantor Subsidiary; and (y) any Subsidiary of Borrower that is an Excluded Subsidiary may be merged with or into Borrower or any other Subsidiary, or be liquidated, wound up or dissolved, or all or any part of its business, property or assets may be conveyed, sold, leased, transferred or otherwise disposed of, in one transaction or a series of transactions, to Borrower or any other Subsidiary; provided, that in each case of clauses (x) and (y), in the case of such merger involving Borrower, Borrower shall be the continuing or surviving Person and in the case of such merger not involving Borrower but involving a Guarantor Subsidiary, a Guarantor Subsidiary shall be the continuing or surviving person; or

(ii) in connection with Permitted Acquisitions and other Permitted Investments; or

(b) enter into or consummate any Asset Sale, in one transaction or a series of transactions, of all or any part of its business, assets or property of any kind whatsoever (including, without limitation, any Product (including, without limitation, any Intellectual Property rights related thereto), any Product Agreement (including, without limitation, any of Borrower's rights thereunder), and any Registration), whether real, personal or mixed and whether tangible or intangible, whether now owned or hereafter acquired, or, except, in each case, pursuant to arms' length transactions on market terms and for fair market value:

(i) Permitted Product Transactions;

(ii) [reserved];

(iii) Permitted Acquisitions and other Permitted Investments;

(iv) the disposition, unwinding or other termination of any Hedging Agreement or any Permitted Equity Derivative or the entry into any Permitted Equity Derivatives;

(v) Asset Sales of inventory in the ordinary course of business;

(vi) Asset Sales of obsolete or worn out, retired or surplus property, whether now owned or hereafter acquired, in the ordinary course of business;

(vii) surrender or waiver of contractual rights and settlement or waiver of contractual or litigation claims in the ordinary course of business;

(viii) Asset Sales to a Loan Party;

(ix) Asset Sales by any Subsidiary that is an Excluded Subsidiary;

(x) Asset Sales consisting of Permitted Liens and permitted Restricted Junior Payments;

(xi) Asset Sales of accounts receivable in connection with the collection or compromise thereof and Asset Sales of Cash Equivalents for cash or other Cash Equivalents;

(xii) other Asset Sales (other than any disposition of Material Contracts, Product (Core), Product (Core) Intellectual Property Rights, Registration with respect to any Product (Core), accounts receivables or inventory in respect of any Product (Core) or any other assets necessary or material to the research, development, use or Commercialization of any Product (Core)) so long as at least 75.0% of the consideration paid in connection therewith shall be cash or Cash Equivalents paid substantially concurrently with consummation of the transaction and shall be in an amount not less than the fair market value of the property disposed of; *provided* that for the purposes of this clause (xii), the following shall be deemed to be cash (x) any securities received by the Loan Parties or any Subsidiary from such transferee that are converted by such Person into cash or Cash Equivalents upon the closing of the applicable disposition, (y) any purchase price adjustment, milestone payment, royalty, earnout, contingent payment, back-end or other deferred payment of a similar nature, and (z) any designated non-cash consideration received in respect of such disposition having an aggregate fair market value, taken together with all other designated non-cash consideration received pursuant to this clause (z) that is at that time outstanding, not to exceed \$[***];

(xiii) Asset Sales of Capital Stock in any Joint Venture to the other holders of Capital Stock in such Joint Venture for fair market value; and

(xiv) other Asset Sales in an aggregate amount not to exceed \$[***].

Notwithstanding anything to the contrary contained herein, (i) no assignment, transfer, contribution, license, sublicense or other disposition of any Product (Core), Product (Core) Intellectual Property Rights or Registration with respect to any Product (Core) is permitted hereunder except as specifically permitted under this Agreement and (ii) during a Restricted Period, no Asset Sale otherwise permitted by the forgoing clauses (i), (iii), (x), (xi), (xii), (xiii) or (xiv) shall be permitted.

Section 6.10 Disposal of Subsidiary Interests. Except for any sale of its interests in the Capital Stock of any of its Subsidiaries in compliance with the provisions of Section 6.9, no Loan Party shall, nor shall it permit any of its Subsidiaries to, in each case solely with respect to the interests of or in Loan Party, (a) directly or indirectly sell, assign, pledge or otherwise encumber or dispose of any Capital Stock of any of its Subsidiaries, except to qualify directors if required by applicable law; or (b) permit any of its Subsidiaries directly or indirectly to sell, assign, pledge or otherwise encumber or dispose of any Capital Stock of any of its Subsidiaries, except to another Loan Party (subject to the restrictions on such disposition otherwise imposed hereunder), or to qualify directors if required by applicable law.

Section 6.11 Sales and Lease Backs. No Loan Party shall, nor shall it permit any of its Subsidiaries to, directly or indirectly, become or remain liable as lessee or as a guarantor or other surety with respect to any lease of any property (whether real, personal or mixed), whether now owned or hereafter acquired, which such Loan Party (a) has sold or transferred or is to sell or to transfer to any other Person (other than Borrower or any of its Subsidiaries) or (b) intends to use for substantially the same purpose as any other property that has been or is to be sold or transferred by such Loan Party to any Person (other than Borrower or any of its Subsidiaries) in connection with such lease.

Section 6.12 Transactions with Shareholders and Affiliates. No Loan Party shall, nor shall it permit any of its Subsidiaries to, directly or indirectly, enter into or permit to exist any transaction (including the purchase, sale, lease or exchange of any property or the rendering of any service), or series of related transactions, with any Affiliate of Borrower or of any such holder with a value in excess \$[***]; provided, that the Loan Parties and their Subsidiaries may enter into or permit to exist any such transaction if Administrative Agent has consented thereto in writing prior to the consummation thereof, provided, further, that the foregoing restrictions shall not apply to any of the following:

- (a) any transaction among the Borrower and its Subsidiaries expressly permitted hereunder;

(b) reasonable and customary fees paid to current or former members of the Board of Directors (or similar governing body) of Borrower and its Subsidiaries;

(c) compensation arrangements for current and former officers and other employees of Borrower and its Subsidiaries entered into in the ordinary course of business; and

(d) transactions (or series of related transactions) that have a value not in excess of \$[***] in the aggregate during the term of this Agreement and that are, in the case of each such transaction (or series of related transactions), on terms that are not less favorable to the Borrower or a Subsidiary in any material respect than would be obtainable by the Borrower or such Subsidiary at such time in a comparable arm's-length transaction with a Person other than an Affiliate (as determined in good faith by the senior management or the board of directors of the Borrower).

Section 6.13 Conduct of Business. From and after the Closing Date, no Loan Party shall, nor shall it permit any of its Subsidiaries to, engage in any material line of business other than the businesses engaged in by such Loan Party or its Subsidiaries on the Closing Date or any business reasonably related, complementary, incidental, ancillary thereto or any reasonable extensions thereto.

Section 6.14 Changes to Certain Agreements and Organizational Documents. No Loan Party shall amend or permit any amendments to any Loan Party's Organizational Documents in a manner that is materially adverse to the Lenders in their capacities as such, including, without limitation, any amendment, modification or change to any of Loan Party's Organizational Documents to effect a division or plan of division pursuant to Section 18-217 of the Delaware Limited Liability Company Act (or any similar statute or provision under applicable law).

Section 6.15 Accounting Methods. The Loan Parties will not and will not permit any of their Subsidiaries to modify or change its fiscal year or its method of accounting (other than as may be required to conform to GAAP).

Section 6.16 Deposit Accounts and Securities Accounts. No Loan Party shall establish or maintain a Deposit Account or a Securities Account that is not subject to a Control Agreement except for Excluded Accounts or as otherwise permitted under Section 5.13.

Section 6.17 Prepayments of Certain Indebtedness. No Loan Party shall, directly or indirectly, voluntarily purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any Indebtedness for borrowed money with an aggregate principal amount outstanding of \$[***] prior to its scheduled due date, other than (a) the Obligations, (b) [reserved], (c) Indebtedness secured by a Permitted Lien if the asset securing such Indebtedness has been sold or otherwise disposed of in accordance with Section 6.9, (d) converting (or exchanging) any Indebtedness to (or for) Qualified Capital Stock of Borrower, (e) issuance of Capital Stock (and cash in lieu of fractional shares in connection with such issuance) of the Borrower in connection with any conversion, exercise, repurchase, exchange, redemption, settlement or early termination or cancellation of Permitted Convertible Indebtedness, (f) the issuance of Permitted Convertible Indebtedness that constitutes Permitted Refinancing Indebtedness in exchange for other Permitted Convertible Indebtedness, (g) the redemption, purchase, exchange, early termination or cancellation of Permitted Convertible Indebtedness in an aggregate principal amount not to exceed the Net Proceeds received by the Borrower from the substantially concurrent issuance of additional Permitted Convertible Indebtedness or Capital Stock in connection with a refinancing of the Permitted Convertible Indebtedness being redeemed, purchased, exchanged, terminated or cancelled; provided that additional Permitted Convertible Indebtedness constitutes Permitted Refinancing Indebtedness, and (h) as permitted under the applicable subordination agreement governing any subordinated Indebtedness.

Section 6.18 Anti-Terrorism Laws. None of the Loan Parties, nor any of their Subsidiaries or agents shall:

- (a) conduct any business or engage in any transaction or dealing with any Blocked Person, including the making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person,
- (b) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to the OFAC Sanctions Programs or other Sanctions, or
- (c) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in the OFAC Sanctions Programs, Sanctions, the USA PATRIOT Act or any other Anti-Terrorism Law.
- (d) Borrower shall deliver to the Lenders certifications as reasonably requested from time to time by any Lender confirming Borrower's compliance with this Section 6.18.

Section 6.19 Anti-Corruption Laws. No Loan Party shall use, or permit any of its Subsidiaries to use, directly or indirectly, any of the proceeds of any Loan for the purpose of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any Anti-Corruption Law.

Section 6.20 Use of Proceeds. The Loan Parties will not and will not permit any of their Subsidiaries to use the proceeds of any Loan to directly, or to any Loan Party's knowledge after due care and inquiry, indirectly, to make any payments to a Sanctioned Entity or a Sanctioned Person, to fund any investments, loans or contributions in, or otherwise make such proceeds available to, a Sanctioned Entity or a Sanctioned Person, to fund any operations, activities or business of a Sanctioned Entity or a Sanctioned Person or in any other manner that would result in a violation of Sanctions by any Person and no part of the proceeds of any Loan will be used directly or, to any Loan Party's knowledge after due care and inquiry, indirectly in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any Sanctions, Anti-Corruption Laws or Anti-Terrorism Laws.

Section 6.21 Products and Patent Rights.

(a) During the term of this Agreement, Borrower and its Subsidiaries shall not, without the prior written consent of the Required Lenders, which consent may be granted or withheld in the Required Lenders' sole discretion, other than any Permitted Product Transaction, sell, assign, out-license, partner or otherwise dispose of economic rights or intellectual property related to any Product in the United States to any Person, or enter into any agreement to do any of the foregoing to the extent the consummation thereof would not result in the repayment in full of the Loans and all other Obligations (other than inchoate indemnity obligations for which no claim has been made) and the termination of the Term Loan Commitments.

ARTICLE VII

GUARANTY

Section 7.1 Guaranty of the Obligations. Subject to the provisions of Section 7.2, Guarantors jointly and severally hereby irrevocably and unconditionally guaranty for the ratable benefit of the Beneficiaries the due and punctual payment in full of all Obligations when the same shall become due, whether at stated maturity, by required prepayment, declaration, acceleration, demand or otherwise (including amounts that would become due but for the operation of the automatic stay under Section 362(a) of the Bankruptcy Code, 11 U.S.C. § 362(a)) (collectively, the "Guaranteed Obligations").

Section 7.2 Contribution by Guarantors. All Guarantors desire to allocate among themselves, in a fair and equitable manner, their obligations arising under this Guaranty. Accordingly, in the event any payment or distribution is made on any date by a Guarantor under this Guaranty such that its Aggregate Payments exceeds its Fair Share as of such date, such Guarantor shall be entitled to a contribution from each of the other Guarantors in an amount sufficient to cause each Guarantor's Aggregate Payments to equal its Fair Share as of such date. "Fair Share" means, with respect to any Guarantor as of any date of determination, an amount equal to (a) the ratio of (i) the Fair Share Contribution Amount with respect to such Guarantor, to (ii) the aggregate of the Fair Share Contribution Amounts with respect to all Guarantors multiplied by, (b) the aggregate amount paid or distributed on or before such date by all Guarantors under this Guaranty in respect of the Guaranteed Obligations. "Fair Share Contribution Amount" means, with respect to any Guarantor as of any date of determination, the maximum aggregate amount of the obligations of such Guarantor under this Guaranty that would not render its obligations hereunder subject to avoidance as a fraudulent transfer or conveyance under Section 548 of Title 11 of the United States Code or any comparable applicable provisions of state law; provided, solely for purposes of calculating the "Fair Share Contribution Amount" with respect to any Guarantor for purposes of this Section 7.2, any assets or liabilities of such Guarantor arising by virtue of any rights to subrogation, reimbursement or indemnification or any rights to or obligations of contribution hereunder shall not be considered as assets or liabilities of such Guarantor. "Aggregate Payments" means, with respect to any Guarantor as of any date of determination, an amount equal to (A) the aggregate amount of all payments and distributions made on or before such date by such Guarantor in respect of this Guaranty (including, without limitation, in respect of this Section 7.2), minus (B) the aggregate amount of all payments received on or before such date by such Guarantor from the other Guarantors as contributions under this Section 7.2. The amounts payable as contributions hereunder shall be determined as of the date on which the related payment or distribution is made by the applicable Guarantor. The allocation among Guarantors of their obligations as set forth in this Section 7.2 shall not be construed in any way to limit the liability of any Guarantor hereunder. Each Guarantor is a third party beneficiary to the contribution agreement set forth in this Section 7.2.

Section 7.3 Payment by Guarantors. Subject to Section 7.2, Guarantors hereby jointly and severally agree, in furtherance of the foregoing and not in limitation of any other right that any Beneficiary may have at law or in equity against any Guarantor by virtue hereof, that upon the failure of Borrower to pay any of the Guaranteed Obligations when and as the same shall become due, whether at stated maturity, by required prepayment, declaration, acceleration, demand or otherwise (including amounts that would become due but for the operation of the automatic stay under Section 362(a) of the Bankruptcy Code, 11 U.S.C. § 362(a)), Guarantors will upon demand pay, or cause to be paid, in Cash, to Administrative Agent for the ratable benefit of Beneficiaries, an amount equal to the sum of the unpaid principal amount of all Guaranteed Obligations then due as aforesaid, accrued and unpaid interest on such Guaranteed Obligations (including interest that, but for Borrower's becoming the subject of a case under the Bankruptcy Code, would have accrued on such Guaranteed Obligations, whether or not a claim is allowed against Borrower for such interest in the related bankruptcy case) and all other Guaranteed Obligations then owed to Beneficiaries as aforesaid.

Section 7.4 Liability of Guarantors Absolute. Each Guarantor agrees that its obligations hereunder are irrevocable, absolute, independent and unconditional and shall not be affected by any circumstance that constitutes a legal or equitable discharge of a guarantor or surety other than payment in full of the Guaranteed Obligations. In furtherance of the foregoing and without limiting the generality thereof, each Guarantor agrees as follows:

(a) this Guaranty is a guaranty of payment when due and not of collectability. This Guaranty is a primary obligation of each Guarantor and not merely a contract of surety;

(b) Administrative Agent may enforce this Guaranty upon the occurrence of an Event of Default notwithstanding the existence of any dispute between Borrower and any Beneficiary with respect to the existence of such Event of Default;

(c) the obligations of each Guarantor hereunder are independent of the obligations of Borrower and the obligations of any other guarantor (including any other Guarantor) of the obligations of Borrower, and a separate action or actions may be brought and prosecuted against such Guarantor whether or not any action is brought against Borrower or any of such other guarantors and whether or not Borrower is joined in any such action or actions;

(d) payment by any Guarantor of a portion, but not all, of the Guaranteed Obligations shall in no way limit, affect, modify or abridge any Guarantor's liability for any portion of the Guaranteed Obligations that has not been paid. Without limiting the generality of the foregoing, if Administrative Agent is awarded a judgment in any suit brought to enforce any Guarantor's covenant to pay a portion of the Guaranteed Obligations, such judgment shall not be deemed to release such Guarantor from its covenant to pay the portion of the Guaranteed Obligations that is not the subject of such suit, and such judgment shall not, except to the extent satisfied by such Guarantor, limit, affect, modify or abridge any other Guarantor's liability hereunder in respect of the Guaranteed Obligations;

(e) any Beneficiary, upon such terms as it deems appropriate, without notice or demand and without affecting the validity or enforceability hereof or giving rise to any reduction, limitation, impairment, discharge or termination of any Guarantor's liability hereunder, from time to time may (i) renew, extend, accelerate, increase the rate of interest on, or otherwise change the time, place, manner or terms of payment of the Guaranteed Obligations; (ii) settle, compromise, release or discharge, or accept or refuse any offer of performance with respect to, or substitutions for, the Guaranteed Obligations or any agreement relating thereto or subordinate the payment of the same to the payment of any other obligations; (iii) request and accept other guaranties of the Guaranteed Obligations and take and hold security for the payment hereof or the Guaranteed Obligations; (iv) release, surrender, exchange, substitute, compromise, settle, rescind, waive, alter, subordinate or modify, with or without consideration, any security for payment of the Guaranteed Obligations, any other guaranties of the Guaranteed Obligations, or any other obligation of any Person (including any other Guarantor) with respect to the Guaranteed Obligations; (v) enforce and apply any security now or hereafter held by or for the benefit of such Beneficiary in respect hereof or the Guaranteed Obligations and direct the order or manner of sale thereof, or exercise any other right or remedy that such Beneficiary may have against any such security, in each case as such Beneficiary in its discretion may determine consistent herewith and any applicable security agreement, including foreclosure on any such security pursuant to one or more judicial or non-judicial sales, whether or not every aspect of any such sale is commercially reasonable, and even though such action operates to impair or extinguish any right of reimbursement or subrogation or other right or remedy of any Guarantor against Borrower or any security for the Guaranteed Obligations; and (vi) exercise any other rights available to it under the Loan Documents; and

(f) this Guaranty and the obligations of Guarantors hereunder shall be valid and enforceable and shall not be subject to any reduction, limitation, impairment, discharge or termination for any reason (other than payment in full in cash of the Guaranteed Obligations), including the occurrence of any of the following, whether or not any Guarantor shall have had notice or knowledge of any of them: (i) any failure or omission to assert or enforce or agreement or election not to assert or enforce, or the stay or enjoining, by order of court, by operation of law or otherwise, of the exercise or enforcement of, any claim or demand or any right, power or remedy (whether arising under the Loan Documents, at law, in equity or otherwise) with respect to the Guaranteed Obligations or any agreement relating thereto, or with respect to any other guaranty of or security for the payment of the Guaranteed Obligations; (ii) any rescission, waiver, amendment or modification of, or any consent to departure from, any of the terms or provisions (including provisions relating to events of default) hereof, any of the other Loan Documents or any agreement or instrument executed pursuant thereto, or of any other guaranty or security for the Guaranteed Obligations, in each case whether or not in accordance with the terms hereof or such Loan Document or any agreement relating to such other guaranty or security; (iii) the Guaranteed Obligations, or any agreement relating thereto, at any time being found to be illegal, invalid or unenforceable in any respect; (iv) the application of payments received from any source (other than payments received pursuant to the other Loan Documents or from the proceeds of any security for the Guaranteed Obligations, except to the extent such security also serves as collateral for indebtedness other than the Guaranteed Obligations) to the payment of indebtedness other than the Guaranteed Obligations, even though any Beneficiary might have elected to apply such payment to any part or all of the Guaranteed Obligations; (v) any Beneficiary's consent to the change, reorganization or termination of the corporate structure or existence of Borrower or any of its Subsidiaries and to any corresponding restructuring of the Guaranteed Obligations; (vi) any failure to perfect or continue perfection of a security interest in any collateral that secures any of the Guaranteed Obligations; (vii) any defenses (other than a defense of payment or performance), set offs or counterclaims that Borrower may allege or assert against any Beneficiary in respect of the Guaranteed Obligations, including failure of consideration, breach of warranty, payment, statute of frauds, statute of limitations, accord and satisfaction and usury; and (viii) any other act or thing or omission, or delay to do any other act or thing, that may or might in any manner or to any extent vary the risk of any Guarantor as an obligor in respect of the Guaranteed Obligations.

Section 7.5 Waivers by Guarantors. Each Guarantor hereby waives, for the benefit of Beneficiaries: (a) any right to require any Beneficiary, as a condition of payment or performance by such Guarantor, to (i) proceed against Borrower, any other guarantor (including any other Guarantor) of the Guaranteed Obligations or any other Person, (ii) proceed against or exhaust any security held from Borrower, any such other guarantor or any other Person, (iii) proceed against or have resort to any balance of any Deposit Account or credit on the books of any Beneficiary in favor of Borrower or any other Person, or (iv) pursue any other remedy in the power of any Beneficiary whatsoever; (b) any defense arising by reason of the incapacity, lack of authority or any disability or other defense of Borrower or any other Guarantor including any defense based on or arising out of the lack of validity or the unenforceability of the Guaranteed Obligations or any agreement or instrument relating thereto or by reason of the cessation of the liability of Borrower or any other Guarantor from any cause other than payment in full in cash of the Guaranteed Obligations; (c) any defense based upon any statute or rule of law that provides that the obligation of a surety must be neither larger in amount nor in other respects more burdensome than that of the principal; (d) any defense based upon any Beneficiary's errors or omissions in the administration of the Guaranteed Obligations, except behavior that amounts to bad faith; (e) (i) any principles or provisions of law, statutory or otherwise that are or might be in conflict with the terms hereof and any legal or equitable discharge of such Guarantor's obligations hereunder, (ii) the benefit of any statute of limitations affecting such Guarantor's liability hereunder or the enforcement hereof, (iii) any rights to set offs, recoupments and counterclaims, and (iv) promptness, diligence and any requirement that any Beneficiary protect, secure, perfect or insure any security interest or lien or any property subject thereto; (f) notices, demands, presentments, protests, notices of protest, notices of dishonor and notices of any action or inaction, including acceptance hereof, notices of default hereunder or any agreement or instrument related thereto, notices of any renewal, extension or modification of the Guaranteed Obligations or any agreement related thereto, notices of any extension of credit to Borrower and notices of any of the matters referred to in Section 7.4 and any right to consent to any thereof; and (g) any defenses or benefits that may be derived from or afforded by law, that limit the liability of or exonerate guarantors or sureties or that may conflict with the terms hereof.

Section 7.6 Guarantors' Rights of Subrogation, Contribution, Etc. Until the Guaranteed Obligations shall have been indefeasibly paid in cash in full, each Guarantor hereby waives any claim, right or remedy, direct or indirect, that such Guarantor now has or may hereafter have against Borrower or any other Guarantor or any of its assets in connection with this Guaranty or the performance by such Guarantor of its obligations hereunder, in each case whether such claim, right or remedy arises in equity, under contract, by statute, under common law or otherwise and including without limitation (a) any right of subrogation, reimbursement or indemnification that such Guarantor now has or may hereafter have against Borrower with respect to the Guaranteed Obligations, (b) any right to enforce, or to participate in, any claim, right or remedy that any Beneficiary now has or may hereafter have against Borrower, and (c) any benefit of, and any right to participate in, any collateral or security now or hereafter held by any Beneficiary. In addition, until the Guaranteed Obligations shall have been indefeasibly paid in full, each Guarantor shall withhold exercise of any right of contribution such Guarantor may have against any other guarantor (including any other Guarantor) of the Guaranteed Obligations, including, without limitation, any such right of contribution as contemplated by Section 7.2. Each Guarantor further agrees that, to the extent the waiver or agreement to withhold the exercise of its rights of subrogation, reimbursement, indemnification and contribution as set forth herein is found by a court of competent jurisdiction to be void or voidable for any reason, any rights of subrogation, reimbursement or indemnification such Guarantor may have against Borrower or against any collateral or security, and any rights of contribution such Guarantor may have against any such other guarantor, shall be junior and subordinate to any rights any Beneficiary may have against Borrower, to all right, title and interest any Beneficiary may have in any such collateral or security, and to any right any Beneficiary may have against such other guarantor. If any amount shall be paid to any Guarantor on account of any such subrogation, reimbursement, indemnification or contribution rights at any time when all Guaranteed Obligations shall not have been finally and indefeasibly paid in full, such amount shall be held in trust for Administrative Agent on behalf of Beneficiaries and shall forthwith be paid over to Administrative Agent for the benefit of Beneficiaries to be credited and applied against the Guaranteed Obligations, whether matured or unmatured, in accordance with the terms hereof.

Section 7.7 Subordination of Other Obligations. Any Indebtedness of Borrower or any Guarantor now or hereafter held by any Guarantor is hereby subordinated in right of payment to the Guaranteed Obligations, and any such indebtedness collected or received by such Guarantor after an Event of Default has occurred and is continuing shall be held in trust for Administrative Agent on behalf of the Beneficiaries and, upon demand by the Administrative Agent, shall forthwith be paid over to Administrative Agent for the benefit of Beneficiaries to be credited and applied against the Guaranteed Obligations but without affecting, impairing or limiting in any manner the liability of such Guarantor under any other provision hereof.

Section 7.8 Continuing Guaranty. This Guaranty is a continuing guaranty and shall remain in effect until all of the Guaranteed Obligations shall have been indefeasibly paid in full. Each Guarantor hereby irrevocably waives any right to revoke this Guaranty as to future transactions giving rise to any Guaranteed Obligations.

Section 7.9 Authority of Guarantors or Borrower. It is not necessary for any Beneficiary to inquire into the capacity or powers of any Guarantor or Borrower or the officers, directors or agents acting or purporting to act on behalf of any of them.

Section 7.10 Financial Condition of Borrower. Any Credit Extension may be made to Borrower or continued from time to time without notice to or authorization from any Guarantor regardless of the financial or other condition of Borrower at the time of any such grant or continuation is entered into, as the case may be. No Beneficiary shall have any obligation to disclose or discuss with any Guarantor its assessment, or any Guarantor's assessment, of the financial condition of Borrower. Each Guarantor has adequate means to obtain information from Borrower on a continuing basis concerning the financial condition of Borrower and its ability to perform its obligations under the Loan Documents, and each Guarantor assumes the responsibility for being and keeping informed of the financial condition of Borrower and of all circumstances bearing upon the risk of non-payment of the Guaranteed Obligations. Each Guarantor hereby waives and relinquishes any duty on the part of any Beneficiary to disclose any matter, fact or thing relating to the business, operations or conditions of Borrower now known or hereafter known by any Beneficiary.

Section 7.11 Bankruptcy, Etc. So long as any Guaranteed Obligations remain outstanding, no Guarantor shall, without the prior written consent of Administrative Agent acting pursuant to the instructions of Required Lenders, commence or join with any other Person in commencing any bankruptcy, reorganization or insolvency case or proceeding of or against Borrower or any other Guarantor. The obligations of Guarantors hereunder shall not be reduced, limited, impaired, discharged, deferred, suspended or terminated by any case or proceeding, voluntary or involuntary, involving the bankruptcy, insolvency, receivership, administration, reorganization, liquidation or arrangement of Borrower or any other Guarantor or by any defense that Borrower or any other Guarantor may have by reason of the order, decree or decision of any court or administrative body resulting from any such proceeding.

(b) Each Guarantor acknowledges and agrees that any interest on any portion of the Guaranteed Obligations that accrues after the commencement of any case or proceeding referred to in clause (a) above (or, if interest on any portion of the Guaranteed Obligations ceases to accrue by operation of law by reason of the commencement of such case or proceeding, such interest as would have accrued on such portion of the Guaranteed Obligations if such case or proceeding had not been commenced) shall be included in the Guaranteed Obligations because it is the intention of Guarantors and Beneficiaries that the Guaranteed Obligations that are guaranteed by Guarantors pursuant hereto should be determined without regard to any rule of law or order that may relieve Borrower of any portion of such Guaranteed Obligations. Guarantors will permit any trustee in bankruptcy, receiver, administrator, debtor in possession, assignee for the benefit of creditors or similar person to pay Administrative Agent, or allow the claim of Administrative Agent in respect of, any such interest accruing after the date on which such case or proceeding is commenced.

(c) In the event that all or any portion of the Guaranteed Obligations are paid by Borrower, the obligations of Guarantors hereunder shall continue and remain in full force and effect or be reinstated, as the case may be, in the event that all or any part of such payment(s) are rescinded or recovered directly or indirectly from any Beneficiary as a preference, fraudulent transfer or otherwise, and any such payments that are so rescinded or recovered shall constitute Guaranteed Obligations for all purposes hereunder.

Section 7.12 Discharge of Guaranty Upon Sale of Guarantor. If all of the Capital Stock of any Guarantor or any of its successors in interest hereunder shall be sold or otherwise disposed of (including by merger or consolidation) or if such Guarantor ceases to be a Subsidiary of the Borrower, in each case, in accordance with the terms and conditions hereof, the Guaranty of such Guarantor or such successor in interest, as the case may be, hereunder shall automatically be discharged and released without any further action by any Beneficiary or any other Person effective as of the time of such Asset Sale.

Section 7.13 ***. ***.

ARTICLE VIII

EVENTS OF DEFAULT

Section 8.1 Events of Default. If any one or more of the following conditions or events shall occur:

(a) Failure to Make Payments When Due. Failure by Borrower to pay (i) the principal of and premium, if any, on any Term Loan when due whether at stated maturity, by acceleration or otherwise; or (ii) within [***] when due any interest on any Term Loan or any fee or any other amount due hereunder; or

(b) Default in Other Agreements. (i) Failure of any Loan Party or any Loan Party's Subsidiaries to pay when due any principal of or interest on or any other amount payable in respect of one or more items of Indebtedness (other than [***]) in an individual principal amount, put price or other accelerated amount of \$[***] or more or with an aggregate principal amount, put price or other accelerated amount of \$[***] or more, in each case beyond the grace period, if any, provided therefor, or (ii) breach or default by any Loan Party with respect to any other material term of (A) one or more items of Indebtedness in the individual or aggregate principal amounts referred to in clause (i) above, or (B) any loan agreement, mortgage, indenture or other agreement relating to such item(s) of Indebtedness, in each case beyond the grace period, if any, provided therefor, if the effect of such breach or default is to cause, or to permit the holder or holders of that Indebtedness (or a trustee on behalf of such holder or holders), to cause, that Indebtedness to become or be declared due and payable (or subject to a compulsory repurchase or redeemable) or to require the prepayment, redemption, repurchase or defeasance of, or to cause Borrower or any of Borrower's Subsidiaries to make any offer to prepay, redeem, repurchase or defease such Indebtedness, prior to its stated maturity or the stated maturity of any underlying obligation, as the case may be; provided that this clause (b) shall not apply to (x) secured Indebtedness that becomes due as a result of the sale or transfer or other Asset Sale (including any casualty proceeds) of the property or assets securing such Indebtedness permitted hereunder and under the documents providing for such Indebtedness and such Indebtedness is repaid when required under the documents providing for such Indebtedness or (y) Indebtedness for which such failure, breach or default has been cured or waived in accordance with the terms of the applicable Indebtedness; or

(c) Breach of Certain Covenants. Failure of any Loan Party to perform or comply with any term or condition contained in Section 2.2, Section 5.1, Section 5.2, Section 5.7, Section 5.8, Section 5.10, Section 5.11, Section 5.13, Section 5.14, or Article VI; or

(d) Breach of Representations, Etc. Any representation, warranty, certification or other statement made or deemed made by any Loan Party in any Loan Document or in any statement or certificate at any time given by any Loan Party or any of their Subsidiaries in writing pursuant hereto or thereto or in connection herewith or therewith shall be false in any material respect (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) as of the date made or deemed made; or

(e) Other Defaults Under Loan Documents. Any Loan Party shall default in the performance of or compliance with any term contained herein or any of the other Loan Documents, other than any such term referred to in any other Section of this Section 8.1, and such default shall not have been remedied or waived within [***] after the earlier of (i) an officer of such Loan Party becoming aware of such default, or (ii) receipt by Borrower of notice from Administrative Agent or any Lender of such default; or

(f) Involuntary Bankruptcy; Appointment of Receiver, Etc. (i) A court of competent jurisdiction shall enter a decree or order for relief in respect of Borrower or any of its Subsidiaries ([***) in an involuntary case under the Bankruptcy Code or under any other applicable bankruptcy, insolvency or similar law now or hereafter in effect, which decree or order is not stayed; or any other similar relief shall be granted under any applicable federal or state law; or (ii) an involuntary case shall be commenced against Borrower or any of its Subsidiaries ([***) under the Bankruptcy Code or under any other applicable bankruptcy, insolvency or similar law now or hereafter in effect; or a decree or order of a court having jurisdiction in the premises for the appointment of a receiver, administrator, liquidator, sequestrator, trustee, custodian or other officer having similar powers over Borrower or any of its Subsidiaries ([***), or over all or a substantial part of its property, shall have been entered; or there shall have occurred the involuntary appointment of an interim receiver, administrator, trustee or other custodian of Borrowers or any of its Subsidiaries ([***) for all or a substantial part of its property; or a warrant of attachment, execution or similar process shall have been issued against any substantial part of the property of Borrower or any of its Subsidiaries (other than any Immaterial Subsidiary), and any such event described in the foregoing clauses (i) or (ii) shall continue for [***) without having been dismissed, bonded or discharged; or

(g) Voluntary Bankruptcy; Appointment of Receiver, Etc. (i) Borrower or any of its Subsidiaries ([***) shall have an order for relief entered with respect to it or shall commence a voluntary case under the Bankruptcy Code or under any other applicable bankruptcy, insolvency or similar law now or hereafter in effect, or shall consent to the entry of an order for relief in an involuntary case, or to the conversion of an involuntary case to a voluntary case, under any such law, or shall consent to the appointment of or taking possession by a receiver, administrator, trustee or other custodian for all or a substantial part of its property; or Borrower or any of its Subsidiaries ([***) shall make any assignment for the benefit of creditors; or (ii) Borrower or any of its Subsidiaries ([***) shall be unable, or shall fail generally, or shall admit in writing its inability, to pay its debts as such debts become due; or the Board of Directors (or similar governing body) of Borrower or any of its Subsidiaries ([***) shall adopt any resolution or otherwise authorize any action to approve any of the actions referred to herein or in Section 8.1(f); or

(h) Judgments and Attachments. Any money judgment, writ or warrant of attachment or similar process involving (a) in any individual case an amount in excess of \$[***) or (b) in the aggregate at any time an amount in excess of \$[***) (in any case to the extent not adequately covered by insurance as to which a solvent and unaffiliated insurance company has not denied coverage) shall be entered or filed against Borrower or any of its Subsidiaries (other than [***) or any of their respective assets and shall remain undischarged, unvacated, unbonded or unstayed for a period of [***)]; or

(i) Dissolution. Any order, judgment or decree shall be entered against the Borrower or any of its Subsidiaries (other than any Immaterial Subsidiary) decreeing the dissolution or split up of such Loan Party or any of its Subsidiaries ([***) and such order shall remain undischarged or unstayed for a period in excess of [***)]; or

(j) Change of Control. A Change of Control shall occur; or

(k) Guaranties, Collateral Documents and other Loan Documents. At any time after the execution and delivery thereof, (i) the Guaranty for any reason, other than the satisfaction in full in cash of all Obligations, shall cease to be in full force and effect (other than in accordance with its terms) or shall be declared to be null and void or any Guarantor shall repudiate its obligations thereunder, (ii) this Agreement or any Collateral Document ceases to be in full force and effect (other than by reason of a release of Collateral in accordance with the terms hereof or thereof or the satisfaction in full in cash of the Obligations in accordance with the terms hereof) or shall be declared null and void, or Administrative Agent shall not have or shall cease to have a valid and perfected Lien in any Collateral purported to be covered by the Collateral Documents with the priority required by the relevant Collateral Document, in each case for any reason other than the failure of Administrative Agent or any Secured Party to take any action within its control, or (iii) any Loan Party shall contest the validity or enforceability of any Loan Document in writing or deny in writing that it has any further liability, including with respect to future advances by Lenders, under any Loan Document to which it is a party; or

(l) Proceedings. The indictment of Borrower or any of its Subsidiaries (other than any Immaterial Subsidiary) under any criminal statute, or commencement of criminal or civil proceedings against Borrower or any of its Subsidiaries (other than any Immaterial Subsidiary) pursuant to which statute or proceedings the penalties or remedies sought or available include forfeiture to any Governmental Authority of any material portion of the property of such Person; or

(m) ERISA. The occurrence of any ERISA Event that, individually or in the aggregate, has resulted or would reasonably be expected to result in a Material Adverse Effect or in the imposition of a Lien; or

(n) Withdrawal Event. The occurrence of a Withdrawal Event; or

(o) Material Contracts. The occurrence of a default, event of default or termination event under the BRIUMVI License Agreement or any agreement set forth on Schedule 1.1(b) hereto.

Section 8.2 Remedies. Upon the occurrence and during the continuance of any Event of Default, Administrative Agent may, and shall at the request of the Required Lenders:

(a) declare the unpaid principal amount of all outstanding Term Loans, all interest accrued and unpaid thereon, and all other amounts owing or payable hereunder or under any other Loan Document to be immediately due and payable; without presentment, demand, protest or other notice of any kind, all of which are hereby expressly waived by each Loan Party; and

(b) exercise on behalf of themselves and the Lenders all rights and remedies available to them and the Lenders under the Loan Documents or applicable law or in equity or under any other instrument, document or agreement now existing or hereafter arising;

provided, that upon the occurrence of any event specified in Section 8.1(f) or (g) above, the unpaid principal amount of all outstanding Term Loans and all interest and other amounts as aforesaid shall automatically become due and payable without further act of Administrative Agent or any Lender.

Section 8.3 Rights Not Exclusive. The rights provided for in this Agreement and the other Loan Documents are cumulative and are not exclusive of any other rights, powers, privileges or remedies provided by law or in equity, or under any other instrument, document or agreement now existing or hereafter arising.

ARTICLE IX

ADMINISTRATIVE AGENT

Section 9.1 Appointment of Administrative Agent.

(a) Blue Owl is hereby appointed Administrative Agent hereunder and under the other Loan Documents and each Lender hereby authorizes Blue Owl, in such capacity, to act as its agent in accordance with the terms hereof and the other Loan Documents to perform, exercise and enforce any and all other rights and remedies of the Lenders with respect to the Loan Parties, the Obligations or otherwise related to any of same to the extent reasonably incidental to the exercise by Administrative Agent of the rights and remedies specifically authorized to be exercised by Administrative Agent by the terms of this Agreement or any other Loan Parties.

(b) Administrative Agent hereby agrees to act upon the express conditions contained herein and the other Loan Documents, as applicable. The provisions of this Article IX (other than Section 9.8(a)(ii)) are solely for the benefit of Administrative Agent and Lenders and no Loan Party shall have any rights as a third party beneficiary of any of the provisions thereof. In performing its functions and duties hereunder, Administrative Agent shall act solely as an agent of Lenders and does not assume and shall not be deemed to have assumed any obligation towards or relationship of agency or trust with or for Borrower or any of its Subsidiaries.

Section 9.2 Powers and Duties. Each Lender irrevocably authorizes Administrative Agent to take such action on such Lender's behalf and to exercise such powers, rights and remedies hereunder and under the other Loan Documents as are specifically delegated or granted to Administrative Agent by the terms hereof and thereof, together with such powers, rights and remedies as are reasonably incidental thereto. Administrative Agent shall have only those duties and responsibilities that are expressly specified herein and the other Loan Documents. Administrative Agent may exercise such powers, rights and remedies and perform such duties by or through its agents or employees Administrative Agent shall not have, by reason hereof or any of the other Loan Documents, a fiduciary relationship in respect of any Lender; and nothing herein or any of the other Loan Documents, expressed or implied, is intended to or shall be so construed as to impose upon Administrative Agent any obligations in respect hereof or any of the other Loan Documents except as expressly set forth herein or therein.

Section 9.3 General Immunity.

(a) No Responsibility for Certain Matters. Administrative Agent shall not be responsible to any Lender for the execution, effectiveness, genuineness, validity, enforceability, collectability or sufficiency hereof or any other Loan Document or for any representations, warranties, recitals or statements made herein or therein or made in any written or oral statements or in any financial or other statements, instruments, reports or certificates or any other documents furnished or made by Administrative Agent to Lenders or by or on behalf of any Loan Party to Administrative Agent or any Lender in connection with the Loan Documents and the transactions contemplated thereby or for the financial condition or business affairs of any Loan Party or any other Person liable for the payment of any Obligations, nor shall Administrative Agent be required to ascertain or inquire as to the performance or observance of any of the terms, conditions, provisions, covenants or agreements contained in any of the Loan Documents or as to the use of the proceeds of the Loans or as to the existence or possible existence of any Event of Default or Default or to make any disclosures with respect to the foregoing. Anything contained herein to the contrary notwithstanding, Administrative Agent shall not have any liability arising from confirmations of the amount of outstanding Term Loans or the component amounts thereof.

(b) Exculpatory Provisions. Neither Administrative Agent nor any of its officers, partners, directors, employees or agents shall be liable to Lenders for any action taken or omitted by Administrative Agent under or in connection with any of the Loan Documents except to the extent caused by Administrative Agent's gross negligence or willful misconduct, as determined by a court of competent jurisdiction in a final, non-appealable order. Administrative Agent shall be entitled to refrain from any act or the taking of any action (including the failure to take an action) in connection herewith or any of the other Loan Documents or from the exercise of any power, discretion or authority vested in it hereunder or thereunder unless and until Administrative Agent shall have received instructions in respect thereof from Required Lenders (or such other Lenders as may be required to give such instructions under Section 10.5) and, upon receipt of such instructions from Required Lenders (or such other Lenders, as the case may be), Administrative Agent shall be entitled to act or (where so instructed) refrain from acting, or to exercise such power, discretion or authority, in accordance with such instructions. Without prejudice to the generality of the foregoing, (i) Administrative Agent shall be entitled to rely, and shall be fully protected in relying, upon any communication, instrument or document believed by it to be genuine and correct and to have been signed or sent by the proper Person or Persons, and shall be entitled to rely and shall be protected in relying on opinions and judgments of attorneys (who may be attorneys for Borrower and its Subsidiaries), accountants, experts and other professional advisors selected by it; and (ii) no Lender shall have any right of action whatsoever against Administrative Agent as a result of Administrative Agent acting or (where so instructed) refraining from acting hereunder or any of the other Loan Documents in accordance with the instructions of Required Lenders (or such other Lenders as may be required to give such instructions under Section 10.5).

(c) Notice of Default. Administrative Agent shall not be deemed to have knowledge or notice of the occurrence of any Default or Event of Default, except with respect to Events of Default in the payment of principal, interest and fees required to be paid to Administrative Agent for the account of the Lenders, unless Administrative Agent shall have received written notice from a Lender or the Loan Party referring to this Agreement, describing such Default or Event of Default and stating that such notice is a "notice of default." Administrative Agent will notify the Lenders of its receipt of any such notice. Administrative Agent shall take such action with respect to any such Default or Event of Default as may be directed by the Required Lenders in accordance with Article VIII; provided, however, that unless and until Administrative Agent has received any such direction, Administrative Agent may (but shall not be obligated to) take such action, or refrain from taking such action, with respect to such Default or Event of Default as it shall deem advisable or in the best interest of the Lenders.

Section 9.4 Administrative Agent Entitled to Act as Lender. The agency hereby created shall in no way impair or affect any of the rights and powers of, or impose any duties or obligations upon, Administrative Agent in its individual capacity as a Lender hereunder. With respect to its participation in the Term Loans, Administrative Agent shall have the same rights and powers hereunder as any other Lender and may exercise the same as if it were not performing the duties and functions delegated to it hereunder, and the term "Lender" shall, unless the context clearly otherwise indicates, include Administrative Agent in its individual capacity. Administrative Agent and its Affiliates may accept deposits from, lend money to, own securities of, and generally engage in any kind of banking, trust, financial advisory or other business with Borrower or any of its Affiliates as if it were not performing the duties specified herein, and may accept fees and other consideration from Borrower for services in connection herewith and otherwise without having to account for the same to Lenders.

Section 9.5 Lenders' Representations, Warranties and Acknowledgment.

(a) Each Lender represents and warrants that it has made its own independent investigation of the financial condition and affairs of Borrower and its Subsidiaries in connection with Credit Extensions hereunder and that it has made and shall continue to make its own appraisal of the creditworthiness of Borrower and its Subsidiaries. Administrative Agent shall not have any duty or responsibility, either initially or on a continuing basis, to make any such investigation or any such appraisal on behalf of Lenders or to provide any Lender with any credit or other information with respect thereto, whether coming into its possession before the making of the Term Loans or at any time or times thereafter, and Administrative Agent shall not have any responsibility with respect to the accuracy of or the completeness of any information provided to Lenders.

(b) Each Lender, by delivering its signature page to this Agreement and funding its Term Loan on the Closing Date, shall be deemed to have acknowledged receipt of, and consented to and approved, each Loan Document and each other document required to be approved by Administrative Agent, Required Lenders or Lenders, as applicable on the Closing Date.

Section 9.6 Right to Indemnity. EACH LENDER, IN PROPORTION TO ITS PRO RATA SHARE, SEVERALLY AGREES TO INDEMNIFY ADMINISTRATIVE AGENT, ITS AFFILIATES AND ITS RESPECTIVE OFFICERS, PARTNERS, DIRECTORS, TRUSTEES, EMPLOYEES AND AGENTS OF ADMINISTRATIVE AGENT (EACH, AN “INDEMNITEE AGENT PARTY”), TO THE EXTENT THAT SUCH INDEMNITEE AGENT PARTY SHALL NOT HAVE BEEN REIMBURSED BY ANY LOAN PARTY, FOR AND AGAINST ANY AND ALL LIABILITIES, OBLIGATIONS, LOSSES, DAMAGES, PENALTIES, ACTIONS, JUDGMENTS, SUITS, COSTS, EXPENSES (INCLUDING COUNSEL FEES AND DISBURSEMENTS) OR DISBURSEMENTS OF ANY KIND OR NATURE WHATSOEVER THAT MAY BE IMPOSED ON, INCURRED BY OR ASSERTED AGAINST SUCH INDEMNITEE AGENT PARTY IN EXERCISING ITS POWERS, RIGHTS AND REMEDIES OR PERFORMING ITS DUTIES HEREUNDER OR UNDER THE OTHER LOAN DOCUMENTS OR OTHERWISE IN ITS CAPACITY AS SUCH INDEMNITEE AGENT PARTY IN ANY WAY RELATING TO OR ARISING OUT OF THIS AGREEMENT OR THE OTHER LOAN DOCUMENTS, **IN ALL CASES, WHETHER OR NOT CAUSED BY OR ARISING, IN WHOLE OR IN PART, OUT OF THE COMPARATIVE, CONTRIBUTORY, OR SOLE NEGLIGENCE OF SUCH INDEMNITEE AGENT PARTY**; PROVIDED, NO LENDER SHALL BE LIABLE FOR ANY PORTION OF SUCH LIABILITIES, OBLIGATIONS, LOSSES, DAMAGES, PENALTIES, ACTIONS, JUDGMENTS, SUITS, COSTS, EXPENSES OR DISBURSEMENTS RESULTING FROM SUCH INDEMNITEE AGENT PARTY’S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, AS DETERMINED BY A COURT OF COMPETENT JURISDICTION IN A FINAL, NON-APPEALABLE ORDER. IF ANY INDEMNITY FURNISHED TO ANY INDEMNITEE AGENT PARTY FOR ANY PURPOSE SHALL, IN THE OPINION OF SUCH INDEMNITEE AGENT PARTY, BE INSUFFICIENT OR BECOME IMPAIRED, SUCH INDEMNITEE AGENT PARTY MAY CALL FOR ADDITIONAL INDEMNITY AND CEASE, OR NOT COMMENCE, TO DO THE ACTS INDEMNIFIED AGAINST UNTIL SUCH ADDITIONAL INDEMNITY IS FURNISHED; PROVIDED, IN NO EVENT SHALL THIS SENTENCE REQUIRE ANY LENDER TO INDEMNIFY ANY INDEMNITEE AGENT PARTY AGAINST ANY LIABILITY, OBLIGATION, LOSS, DAMAGE, PENALTY, ACTION, JUDGMENT, SUIT, COST, EXPENSE OR DISBURSEMENT IN EXCESS OF SUCH LENDER’S PRO RATA SHARE THEREOF; AND PROVIDED FURTHER, THIS SENTENCE SHALL NOT BE DEEMED TO REQUIRE ANY LENDER TO INDEMNIFY ANY INDEMNITEE AGENT PARTY AGAINST ANY LIABILITY, OBLIGATION, LOSS, DAMAGE, PENALTY, ACTION, JUDGMENT, SUIT, COST, EXPENSE OR DISBURSEMENT DESCRIBED IN THE PROVISIO IN THE IMMEDIATELY PRECEDING SENTENCE.

Section 9.7 Successor Administrative Agent.

(a) Administrative Agent may resign at any time by giving [***] days' (or such shorter period as shall be agreed by the Required Lenders) prior written notice thereof to Lenders and Borrower. Upon any such notice of resignation, Required Lenders shall have the right, upon [***] Business Days' notice to Borrower, to appoint a successor Administrative Agent. If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within [***] days after the retiring Administrative Agent gives notice of its resignation, then the retiring Administrative Agent may, on behalf of the Lenders appoint a successor Administrative Agent from among the Lenders. Upon the acceptance of any appointment as Administrative Agent hereunder by a successor Administrative Agent that successor Administrative Agent shall thereupon succeed to and become vested with all the rights, powers, privileges and duties of the retiring Administrative Agent, and the retiring Administrative Agent shall promptly (i) transfer to such successor Administrative Agent all sums, securities or Capital Stock and other items of Collateral held under the Collateral Documents, together with all records and other documents necessary or appropriate in connection with the performance of the duties of the successor Administrative Agent under the Loan Documents, and (ii) execute and deliver to such successor Administrative Agent such amendments to financing statements, and take such other actions, as may be necessary or appropriate in connection with the assignment to such successor Administrative Agent of the security interests created under the Collateral Documents, whereupon such retiring Administrative Agent shall be discharged from its duties and obligations hereunder. After any retiring Administrative Agent's resignation hereunder as Administrative Agent, the provisions of this Article IX shall inure to its benefit as to any actions taken or omitted to be taken by it while it was Administrative Agent hereunder.

(b) Notwithstanding anything herein to the contrary, Administrative Agent may assign its rights and duties as Administrative Agent, as applicable, hereunder to an Affiliate of Blue Owl without the prior written consent of, or prior written notice to, Borrower or the Lenders; provided that Borrower and the Lenders may deem and treat such assigning Administrative Agent as Administrative Agent for all purposes hereof, unless and until such assigning Administrative Agent provides written notice to Borrower and the Lenders of such assignment. Upon such assignment such Affiliate shall succeed to and become vested with all rights, powers, privileges and duties as Administrative Agent hereunder and under the other Loan Documents.

(c) Administrative Agent may perform any and all of its duties and exercise its rights and powers under this Agreement or under any other Loan Document by or through any one or more sub-agents appointed by Administrative Agent. Administrative Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Affiliates. The exculpatory, indemnification and other provisions of Section 9.3, Section 9.6 and of this Section 9.7 shall apply to any of the Affiliates of Administrative Agent. All of the rights, benefits and privileges (including the exculpatory and indemnification provisions) of Section 9.3, Section 9.6 and of this Section 9.7 shall apply to any such sub-agent and to the Affiliates of any such sub-agent and shall apply to their respective activities as sub-agent as if such sub-agent and Affiliates were named herein. Notwithstanding anything herein to the contrary, with respect to each permitted sub-agent appointed by Administrative Agent, (i) such sub-agent shall be a third party beneficiary under this Agreement with respect to all such rights, benefits and privileges (including exculpatory and rights to indemnification) and shall have all of the rights, benefits and privileges of a third party beneficiary, including an independent right of action to enforce such rights, benefits and privileges (including exculpatory rights and rights to indemnification) directly, without the consent or joinder of any other Person, against any or all of the Loan Parties and the Lenders, (ii) such rights, benefits and privileges (including exculpatory rights and rights to indemnification) shall not be modified or amended without the consent of such sub-agent, and (iii) such sub-agent shall only have obligations to Administrative Agent and not to any Loan Party, Lender or any other Person and no Loan Party, Lender or any other Person shall have the rights, directly or indirectly, as a third party beneficiary or otherwise, against such sub-agent.

Section 9.8 Collateral Documents and Guaranty.

(a) Administrative Agent under Collateral Documents and Guaranty. Each Lender hereby further authorizes Administrative Agent on behalf of and for the benefit of Lenders, to be the agent for and representative of Lenders with respect to the Guaranty, the Collateral and the Collateral Documents. Subject to Section 10.5, without further written consent or authorization from Lenders, Administrative Agent (i) may execute any documents or instruments necessary to (A) release any Lien encumbering any item of Collateral that is the subject of an Asset Sale or other sale or disposition of assets permitted hereby or to which Required Lenders (or such other Lenders as may be required to give such consent under Section 10.5) have otherwise consented, or (B) release any Guarantor from the Guaranty pursuant to Section 7.12 or with respect to which Required Lenders (or such other Lenders as may be required to give such consent under Section 10.5) have otherwise consented and (ii) shall, if requested by Borrower, enter into customary intercreditor or non-disturbance agreements, in form and substance reasonably satisfactory to the Administrative Agent, in connection with the entry by Borrower or any Subsidiary into any exclusive out-license that constitutes a Permitted Product Agreement; provided, that prior to or concurrently with making any request pursuant to this Section 9.8(a)(ii), Borrower shall have used commercially reasonable efforts to negotiate the Permitted Product Agreement without an intercreditor agreement (and shall provide Administrative Agent reasonable documentation of the same).

(b) Right to Realize on Collateral and Enforce Guaranty. Anything contained in any of the Loan Documents to the contrary notwithstanding, Borrower, Administrative Agent and each Lender hereby agree that (i) no Lender shall have any right individually to realize upon any of the Collateral or to enforce the Guaranty, it being understood and agreed that all powers, rights and remedies hereunder may be exercised solely by Administrative Agent, on behalf of Lenders in accordance with the terms hereof and all powers, rights and remedies under the Collateral Documents may be exercised solely by Administrative Agent, and (ii) in the event of a foreclosure by Administrative Agent on any of the Collateral pursuant to a public or private sale or any sale of the Collateral in a case under the Bankruptcy Code, Administrative Agent or any Lender may be the purchaser of any or all of such Collateral at any such sale and Administrative Agent, as agent for and representative of Secured Parties (but not any Lender or Lenders in its or their respective individual capacities unless Required Lenders shall otherwise agree in writing) shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such public sale, to use and apply any of the Obligations as a credit on account of the purchase price for any collateral payable by Administrative Agent at such sale.

Section 9.9 Agency for Perfection. Administrative Agent and each Lender hereby appoints each other Lender as agent and bailee for the purpose of perfection the security interests in and liens upon the Collateral in assets that, in accordance with Article 9 of the UCC, can be perfected only by possession or control (or where the security interest of a secured party with possession or control has priority over the security interest of another secured party) and Administrative Agent and each Lender hereby acknowledges that it holds possession of or otherwise controls any such Collateral for the benefit of the Lenders as secured party. Should any Lender obtain possession or control of any such Collateral, such Lender shall notify Administrative Agent thereof, and, promptly upon Administrative Agent's request therefore shall deliver such Collateral to Administrative Agent or in accordance with Administrative Agent's instructions. In addition, Administrative Agent shall also have the power and authority hereunder to appoint such other sub-agents as may be necessary or required under applicable state law or otherwise to perform its duties and enforce its rights with respect to the Collateral and under the Loan Documents. Each Loan Party by its execution and delivery of this Agreement hereby consents to the foregoing.

Section 9.10 Reports and Other Information; Confidentiality; Disclaimers. By becoming a party to this Agreement, each Lender:

(a) is deemed to have requested that Administrative Agent furnish such Lender or Administrative Agent, promptly after it becomes available, a copy of each field audit or examination report with respect to Borrower or its Subsidiaries (each a "Report" and collectively, "Reports") prepared by or at the request of Administrative Agent, and Administrative Agent shall so furnish each Lender with such Reports,

(b) expressly agrees and acknowledges that Administrative Agent does not (i) make any representation or warranty as to the accuracy of any Report, and (ii) shall not be liable for any information contained in any Report,

(c) expressly agrees and acknowledges that the Reports are not comprehensive audits or examinations, that Administrative Agent or other party performing any audit or examination will inspect only specific information regarding Borrower and its Subsidiaries and will rely significantly upon Borrower's and its Subsidiaries' books and records, as well as on representations of such Person's personnel,

(d) agrees to keep all Reports and other material, non-public information regarding Borrower and its Subsidiaries and their operations, assets, and existing and contemplated business plans in a confidential manner in accordance with Section 10.19, and

(e) without limiting the generality of any other indemnification provision contained in this Agreement, agrees: (i) to hold Administrative Agent and any other Lender preparing a Report harmless from any action the indemnifying Lender may take or fail to take or any conclusion the indemnifying Lender may reach or draw from any Report in connection with any loans or other credit accommodations that the indemnifying Lender has made or may make to Borrower, or the indemnifying Lender's participation in, or the indemnifying Lender's purchase of, a loan or loans of Borrower, and (ii) to pay and protect, and indemnify, defend and hold Administrative Agent, and any such other Lender preparing a Report harmless from and against, the claims, actions, proceedings, damages, costs, expenses, and other amounts (including attorneys' fees and costs pursuant to Sections 10.2 or 10.3) incurred by Administrative Agent and any such other Lender or agent preparing a Report as the direct or indirect result of any third parties who might obtain all or part of any Report through the indemnifying Lender or Administrative Agent.

In addition to the foregoing: (x) any Lender may from time to time request of Administrative Agent in writing that Administrative Agent provide to such Lender a copy of any report or document provided by Borrower or its Subsidiaries to Administrative Agent that has not been contemporaneously provided by Borrower or such Subsidiary to such Lender, and, upon receipt of such request, Administrative Agent promptly shall provide a copy of same to such Lender, (y) to the extent that Administrative Agent is entitled, under any provision of the Loan Documents, to request additional reports or information from Borrower or its Subsidiaries, any Lender may, from time to time, reasonably request Administrative Agent to exercise such right as specified in such Lender's notice to Administrative Agent, whereupon Administrative Agent promptly shall request of Borrower the additional reports or information reasonably specified by such Lender, and, upon receipt thereof from Borrower or such Subsidiary, Administrative Agent promptly shall provide a copy of same to such Lender, and (z) any time that Administrative Agent renders to Borrower a statement regarding the Loan Account, Administrative Agent shall send a copy of such statement to each Lender.

Section 9.11 Protective Advances. Subject to the limitations set forth below, upon the occurrence and during the continuance of an Event of Default, Administrative Agent is authorized by Borrower and the Lenders, from time to time in Administrative Agent's sole discretion (but Administrative Agent shall have absolutely no obligation to), to make disbursements or advances to Borrower, which Administrative Agent, in its sole discretion, deems necessary or desirable (i) to preserve or protect the Collateral, or any portion thereof, (ii) to enhance the likelihood of, or maximize the amount of, repayment of the Loans and other Obligations, or (iii) to pay any other amount chargeable to or required to be paid by Borrower pursuant to the terms of this Agreement and the other Loan Documents, including, without limitation, payments of principal, interest, fees and reimbursable expenses (any of such Loans are in this clause (c) referred to as "Protective Advances"). Protective Advances may be made even if the conditions precedent set forth in Article III have not been satisfied. The interest rate on all Protective Advances shall be at the Base Rate plus the Applicable Margin. Each Protective Advance shall be secured by the Liens in favor of the Administrative Agent in and to the Collateral and shall constitute Obligations hereunder. The Protective Advances shall constitute Obligations hereunder that may be charged to the Loan Account in accordance with Section 2.12(i). Borrower shall pay the unpaid principal amount and all unpaid and accrued interest of each Protective Advance on the earlier of the Term Loan Maturity Date and the date on which demand for payment is made by Administrative Agent. Administrative Agent shall notify each Lender and Borrower in writing of each such Protective Advance, which notice shall include a description of the purpose of such Protective Advance. Without limitation to its obligations pursuant to Section 9.6, each Lender agrees that it shall make available to Administrative Agent, upon such Administrative Agent's demand, in Dollars in immediately available funds, the amount equal to such Lender's Pro Rata Share of each such Protective Advance. If such funds are not made available to Administrative Agent by such Lender, Administrative Agent shall be entitled to recover such funds on demand from such Lender, together with interest thereon for each day from the date such payment was due until the date such amount is paid to Administrative Agent, at the Federal Funds Effective Rate for three (3) Business Days and thereafter at the Base Rate.

Section 9.12 Erroneous Payments.

(a) If Administrative Agent (x) notifies a Lender or any Person who has received funds on behalf of a Lender (any such Lender or other recipient (and each of their respective successors and assigns), a “Payment Recipient”) that Administrative Agent has determined in its sole discretion (whether or not after receipt of any notice under immediately succeeding clause (b)) that any funds (as set forth in such notice from Administrative Agent) received by such Payment Recipient from Administrative Agent or any of its Affiliates were erroneously or mistakenly transmitted to, or otherwise erroneously or mistakenly received by, such Payment Recipient (whether or not known to such Lender or other Payment Recipient on its behalf) (any such funds, whether transmitted or received as a payment, prepayment or repayment of principal, interest, fees, distribution or otherwise, individually and collectively, an “Erroneous Payment”) and (y) demands in writing the return of such Erroneous Payment (or a portion thereof), such Erroneous Payment shall at all times remain the property of Administrative Agent pending its return or repayment as contemplated below in this Section 9.12 and held in trust for the benefit of Administrative Agent, and such Lender shall (or, with respect to any Payment Recipient who received such funds on its behalf, shall cause such Payment Recipient to) promptly, but in no event later than two (2) Business Days thereafter (or such later date as Administrative Agent may, in its sole discretion, specify in writing), return to Administrative Agent the amount of any such Erroneous Payment (or portion thereof) as to which such a demand was made, in same day funds (in the currency so received), together with interest thereon (except to the extent waived in writing by the Administrative Agent) in respect of each day from and including the date such Erroneous Payment (or portion thereof) was received by such Payment Recipient to the date such amount is repaid to the Administrative Agent in same day funds at the greater of the Federal Funds Rate and a rate determined by the Administrative Agent in accordance with banking industry rules on interbank compensation from time to time in effect. A notice of Administrative Agent to any Payment Recipient under this clause (a) shall be conclusive, absent manifest error.

(b) Without limiting immediately preceding clause (a), each Lender or any Person who has received funds on behalf of a Lender (and each of their respective successors and assigns), agrees that if it receives a payment, prepayment or repayment (whether received as a payment, prepayment or repayment of principal, interest, fees, distribution or otherwise) from the Administrative Agent (or any of its Affiliates) (x) that is in a different amount than, or on a different date from, that specified in this Agreement or in a notice of payment, prepayment or repayment sent by the Administrative Agent (or any of its Affiliates) with respect to such payment, prepayment or repayment, (y) that was not preceded or accompanied by a notice of payment, prepayment or repayment sent by the Administrative Agent (or any of its Affiliates), or (z) that such Lender or other such recipient, otherwise becomes aware was transmitted, or received, in error or by mistake (in whole or in part), then in each such case:

(i) it acknowledges and agrees that (A) in the case of immediately preceding clauses (x) or (y), an error and mistake shall be presumed to have been made (absent written confirmation from Administrative Agent to the contrary) or (B) an error and mistake has been made (in the case of immediately preceding clause (z)), in each case, with respect to such payment, prepayment or repayment; and

(ii) such Lender shall (and shall use commercially reasonable efforts to cause any other recipient that receives funds on its respective behalf to) promptly (and, in all events, within one (1) Business Day of its knowledge of the occurrence of any of the circumstances described in immediately preceding clauses (x), (y) and (z)) notify Administrative Agent of its receipt of such payment, prepayment or repayment, the details thereof (in reasonable detail) and that it is so notifying Administrative Agent pursuant to this Section 9.12(b).

For the avoidance of doubt, the failure to deliver a notice to Administrative Agent pursuant to this Section 9.12(b) shall not have any effect on a Payment Recipient's obligations pursuant to Section 9.12(a) or on whether or not an Erroneous Payment has been made.

(c) Each Lender hereby authorizes Administrative Agent to set off, net and apply any and all amounts at any time owing to such Lender under any Loan Document, or otherwise payable or distributable by Administrative Agent to such Lender under any Loan Document with respect to any payment of principal, interest, fees or other amounts, against any amount that Administrative Agent has demanded to be returned under immediately preceding clause (a).

(d) The parties hereto agree that (x) irrespective of whether Administrative Agent may be equitably subrogated, in the event that an Erroneous Payment (or portion thereof) is not recovered from any Payment Recipient that has received such Erroneous Payment (or portion thereof) for any reason, the Administrative Agent shall be subrogated to all the rights and interests of such Payment Recipient (and, in the case of any Payment Recipient who has received funds on behalf of a Lender, to the rights and interests of such Lender, as the case may be) under the Loan Documents with respect to such amount (the "Erroneous Payment Subrogation Rights") and (y) an Erroneous Payment shall not pay, prepay, repay, discharge or otherwise satisfy any Obligations owed by the Borrower; provided that this Section 9.12 shall not be interpreted to increase (or accelerate the due date for), or have the effect of increasing (or accelerating the due date for), the Obligations of the Borrower relative to the amount (or timing for payment) of the Obligations that would have been payable had such Erroneous Payment not been made by Administrative Agent; provided, further, that for the avoidance of doubt, immediately preceding clauses (x) and (y) shall not apply to the extent any such Erroneous Payment is, and solely with respect to the amount of such Erroneous Payment that is, comprised of funds received by Administrative Agent from, or on behalf of (including through the exercise of remedies under any Loan Document), the Borrower for the purpose of a payment on the Obligations.

(e) To the extent permitted by applicable law, no Payment Recipient shall assert any right or claim to an Erroneous Payment, and hereby waives, and is deemed to waive, any claim, counterclaim, defense or right of set-off or recoupment with respect to any demand, claim or counterclaim by Administrative Agent for the return of any Erroneous Payment received, including, without limitation, any defense based on "discharge for value" or any similar doctrine.

(f) Each party's obligations, agreements and waivers under this Section 9.12 shall survive the resignation or replacement of Administrative Agent, any transfer of rights or obligations by, or the replacement of, a Lender, or the repayment, satisfaction or discharge of all Obligations (or any portion thereof) under any Loan Document.

ARTICLE X

MISCELLANEOUS

Section 10.1 Notices.

(a) Notices Generally. Unless otherwise specifically provided herein, any notice or other communication herein required or permitted to be given to a Loan Party or Administrative Agent, shall be sent to such Person's address as set forth on Appendix B or in the other relevant Loan Document, and in the case of any Lender, the address as indicated on Appendix B or otherwise indicated to Administrative Agent in writing. Each notice hereunder shall be in writing and may be personally served, telexed or sent by facsimile or United States mail or courier service and shall be deemed to have been given when delivered in person or by courier service and signed for against receipt thereof, upon receipt of facsimile, or three (3) Business Days after depositing it in the United States mail with postage prepaid and properly addressed; provided, no notice to Administrative Agent shall be effective until received by Administrative Agent.

(b) Electronic Communications.

(i) Administrative Agent and Borrower may, in its discretion, agree to accept notices and other communications to it hereunder by electronic communications pursuant to procedures approved by it; provided that approval of such procedures may be limited to particular notices or communications. Notices and other communications to the Lenders hereunder may be delivered or furnished by electronic communication (including e-mail and Internet or intranet websites) pursuant to procedures approved by Administrative Agent, provided that the foregoing shall not apply to notices to any Lender pursuant to Article II if such Lender has notified Administrative Agent that it is incapable of receiving notices under such Article by electronic communication.

(ii) Unless Administrative Agent otherwise prescribes, (A) notices and other communications sent to an e-mail address shall be deemed received upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested" function, as available, return e-mail or other written acknowledgement), and (B) notices or communications posted to an Internet or intranet website shall be deemed received upon the deemed receipt by the intended recipient, at its e-mail address as described in the foregoing clause (A), of notification that such notice or communication is available and identifying the website address therefor; provided that, for both clauses (A) and (B) above, if such notice, email or other communication is not sent during the normal business hours of the recipient, such notice or communication shall be deemed to have been sent at the opening of business on the next Business Day for the recipient.

Section 10.2 Expenses. Whether or not the transactions contemplated hereby shall be consummated, Borrower agrees to pay promptly (or, in the case of costs, fees, expenses and disbursements incurred after the Closing Date, within [***] days of receipt of an invoice) (a) all of Administrative Agent's actual, reasonable and documented out-of-pocket costs and expenses of preparation, negotiation, execution and administration of the Loan Documents and any consents, amendments, waivers or other modifications thereto; (b) all the actual, reasonable and documented out-of-pocket fees, expenses and disbursements of counsel to Administrative Agent in connection with the negotiation, preparation, execution and administration of the Loan Documents and any consents, amendments, waivers or other modifications thereto and any other documents or matters requested by Borrower; (c) all the actual, reasonable and documented out-of-pocket costs and expenses of creating and perfecting Liens in favor of Administrative Agent, for the benefit of Secured Parties, including filing and recording fees, expenses and taxes, stamp or documentary taxes, search fees, title insurance premiums and reasonable and documented out-of-pocket fees, expenses and disbursements of counsel to Administrative Agent and of counsel providing any opinions that Administrative Agent or Required Lenders may request in respect of the Collateral or the Liens created pursuant to the Collateral Documents; (d) all of Administrative Agent's actual, reasonable and documented out-of-pocket fees, expenses for, and disbursements of any of Administrative Agent's auditors, accountants, consultants or appraisers, and all reasonable attorneys' fees incurred by Administrative Agent; (e) all the actual, reasonable and documented out-of-pocket costs and expenses (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any appraisers, consultants, advisors and agents employed or retained by Administrative Agent and its counsel (in each case, external only)) in connection with the custody or preservation of any of the Collateral; (f) all the actual, reasonable and documented out-of-pocket costs and expenses of Administrative Agent and Lenders in connection with the attendance at any meetings in connection with this Agreement and the other Loan Documents (including the meetings referred to in Section 5.7); (g) all other actual, reasonable and documented costs and expenses incurred by Administrative Agent in connection with the syndication of the Loans and Commitments and the negotiation, preparation and execution of the Loan Documents and any consents, amendments, waivers or other modifications thereto and the transactions contemplated thereby; and (h) after the occurrence of a Default or an Event of Default, all costs and expenses, including reasonable and documented out-of-pocket attorneys' fees and costs of settlement, incurred by Administrative Agent and Lenders in enforcing any Obligations of or in collecting any payments due from any Loan Party hereunder or under the other Loan Documents by reason of such Default or Event of Default (including in connection with the sale of, collection from, or other realization upon any of the Collateral or the enforcement of the Guaranty) or in connection with any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work out" or pursuant to any insolvency or bankruptcy cases or proceedings. In each case, in the case of counsel, Borrower will only be required to reimburse expenses of one firm of counsel (in the absence of an actual or perceived conflict), one additional local counsel in each relevant jurisdiction, one intellectual property counsel and such other special counsel subject in the case of such other special counsel to Borrower's consent (such consent not to be unreasonably withheld, conditioned or delayed).

Section 10.3 Indemnity.

(a) IN ADDITION TO THE PAYMENT OF EXPENSES PURSUANT TO SECTION 10.2, WHETHER OR NOT THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE CONSUMMATED, EACH LOAN PARTY AGREES TO DEFEND (SUBJECT TO INDEMNITEES' SELECTION OF COUNSEL), INDEMNIFY, PAY AND HOLD HARMLESS, ADMINISTRATIVE AGENT AND LENDER, THEIR AFFILIATES AND THEIR RESPECTIVE OFFICERS, PARTNERS, DIRECTORS, TRUSTEES, EMPLOYEES AND AGENTS OF ADMINISTRATIVE AGENT AND EACH LENDER (EACH, AN "INDEMNITEE"), FROM AND AGAINST ANY AND ALL INDEMNIFIED LIABILITIES, **IN ALL CASES, WHETHER OR NOT CAUSED BY OR ARISING, IN WHOLE OR IN PART, OUT OF THE COMPARATIVE, CONTRIBUTORY, OR SOLE NEGLIGENCE OF SUCH INDEMNITEE**; PROVIDED, NO LOAN PARTY SHALL HAVE ANY OBLIGATION TO ANY INDEMNITEE HEREUNDER WITH RESPECT TO ANY INDEMNIFIED LIABILITIES TO THE EXTENT SUCH INDEMNIFIED LIABILITIES ARISE FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, AS DETERMINED BY A COURT OF COMPETENT JURISDICTION IN A FINAL, NON-APPEALABLE ORDER, OF THAT INDEMNITEE. TO THE EXTENT THAT THE UNDERTAKINGS TO DEFEND, INDEMNIFY, PAY AND HOLD HARMLESS SET FORTH IN THIS SECTION 10.3 MAY BE UNENFORCEABLE IN WHOLE OR IN PART BECAUSE THEY ARE VIOLATIVE OF ANY LAW OR PUBLIC POLICY, THE APPLICABLE LOAN PARTY SHALL CONTRIBUTE THE MAXIMUM PORTION THAT IT IS PERMITTED TO PAY AND SATISFY UNDER APPLICABLE LAW TO THE PAYMENT AND SATISFACTION OF ALL INDEMNIFIED LIABILITIES INCURRED BY INDEMNITEES OR ANY OF THEM. THIS SECTION 10.3 SHALL NOT APPLY WITH RESPECT TO TAXES OTHER THAN ANY TAXES THAT REPRESENT LOSSES, CLAIMS, DAMAGES, ETC. ARISING FROM ANY NON-TAX CLAIM.

(b) To the extent permitted by applicable law, no Loan Party shall assert, and each Loan Party hereby waives, any claim against Lenders, Administrative Agent and their respective Affiliates, directors, employees, attorneys or agents, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, any Loan or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and Borrower hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor. Notwithstanding any provision in this Section 10.3 to the contrary, no Loan Party shall have any liability under this Section 10.3 for any special, indirect, consequential or punitive damages (as opposed to direct or actual damages), except that, nothing in this sentence shall limit the Loan Party's obligation to indemnify and hold harmless the Indemnitee for any third party claims for which the Indemnitees are entitled to be held harmless and indemnified pursuant to this Section 10.3.

Section 10.4 Set-Off. In addition to any rights now or hereafter granted under applicable law and not by way of limitation of any such rights, upon the occurrence of any Event of Default each Lender, and their respective Affiliates is hereby authorized by each Loan Party at any time or from time to time subject to the consent of Administrative Agent (such consent not to be unreasonably withheld or delayed), without notice to any Loan Party or to any other Person (other than Administrative Agent), any such notice being hereby expressly waived, to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts (in whatever currency)) and any other Indebtedness at any time held or owing by such Lender to or for the credit or the account of any Loan Party (in whatever currency) against and on account of the obligations and liabilities of any Loan Party to such Lender hereunder, the participations under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto, or with any other Loan Document, irrespective of whether or not (a) such Lender shall have made any demand hereunder, (b) the principal of or the interest on the Term Loans or any other amounts due hereunder shall have become due and payable pursuant to Article II and although such obligations and liabilities, or any of them, may be contingent or unmatured or (c) such obligation or liability is owed to a branch or office of such Lender different from the branch or office holding such deposit or obligation or such Indebtedness.

Section 10.5 Amendments and Waivers.

(a) Required Lenders' Consent. Subject to Section 10.5(b), no amendment, modification, termination or waiver of any provision of the Loan Documents, or consent to any departure by any Loan Party therefrom, shall in any event be effective without the written consent of Administrative Agent and the Required Lenders.

(b) Affected Lenders' Consent. Without the written consent of each Lender (other than a Defaulting Lender) directly affected thereby, no amendment, modification, termination, or consent shall be effective if the effect thereof would:

(i) extend the scheduled final maturity of any Loan or Note;

(ii) waive, reduce or postpone any scheduled repayment (but not prepayment);

(iii) reduce the rate of interest on any Loan (other than any waiver of any increase in the interest rate applicable to any Loan pursuant to Section 2.6) or any fee payable hereunder;

(iv) extend the time for payment of any such interest or fees;

(v) reduce the principal amount of any Loan;

(vi) amend, modify, terminate or waive any provision of this Section 10.5(b);

(vii) amend the definition of "Required Lenders" or "Pro Rata Share";

(viii) release all or substantially all of the Collateral or all or substantially all of the Guarantors from the Guaranty except as expressly provided in the Loan Documents;

(ix) (x) subordinate any of the Obligations or (y) any Lien created by this Agreement or any other Loan Document, except, in the case of this clause (y), Permitted Product Transaction or other transaction expressly permitted hereunder that is contemplated to have priority over the Liens securing the Obligations; or

(x) consent to the assignment or transfer by any Loan Party of any of its rights and obligations under any Loan Document.

(c) Other Consents. No amendment, modification, termination or waiver of any provision of the Loan Documents, or consent to any departure by any Loan Party therefrom, shall amend, modify, terminate or waive any provision of Article IX as the same applies to Administrative Agent, or any other provision hereof as the same applies to the rights or obligations of Administrative Agent, in each case without the consent of Administrative Agent.

(d) Execution of Amendments, Etc. Administrative Agent may, but shall have no obligation to, with the consent of any Lender, execute amendments, modifications, waivers or consents on behalf of such Lender. Any waiver or consent shall be effective only in the specific instance and for the specific purpose for which it was given. No notice to or demand on any Loan Party in any case shall entitle any Loan Party to any other or further notice or demand in similar or other circumstances. Any amendment, modification, termination, waiver or consent effected in accordance with this Section 10.5 shall be binding upon each Lender at the time outstanding, each future Lender and, if signed by a Loan Party, on such Loan Party.

Section 10.6 Successors and Assigns; Participations.

(a) Generally. This Agreement shall be binding upon the parties hereto and their respective successors and assigns and shall inure to the benefit of the parties hereto and the successors and assigns of Lenders. No Loan Party's rights or obligations hereunder nor any interest therein may be assigned or delegated by any Loan Party without the prior written consent of all Lenders. Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, Indemnitor Agent Parties under Section 9.6, Indemnitees under Section 10.3, their respective successors and assigns permitted hereby and, to the extent expressly contemplated hereby, Affiliates of each of Administrative Agent and Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) Maintenance of the Register. Borrower, Administrative Agent and Lenders shall, in accordance with the Register provisions of Section 2.3(b), deem and treat the Persons listed as Lenders in the Register as the holders and owners of the corresponding Commitments and Loans listed therein for all purposes hereof, and no assignment or transfer of any such Term Loan Commitment or Loan shall be effective, in each case, unless and until an Assignment Agreement effecting the assignment or transfer thereof shall have been delivered to and accepted by Administrative Agent and recorded in the Register as provided in Section 10.6(e). Prior to such recordation, all amounts owed with respect to the applicable Term Loan Commitment or Loan shall be owed to the Lender listed in the Register as the owner thereof.

(c) Right to Assign. Each Lender shall have the right at any time to sell, assign or transfer all or a portion of its rights and obligations under this Agreement, including, without limitation, all or a portion of its Term Loan Commitment or Loans owing to it or other Obligations (provided, however, that each such assignment shall be of a uniform, and not varying, percentage of all rights and obligations under and in respect of any Loan and any related Commitments):

(i) to any Person (other than a Disqualified Institution) meeting the criteria of clause (a) of the definition of the term of “Eligible Assignee” upon the giving of notice to Borrower and Administrative Agent;

(ii) to any Person constituting an Eligible Assignee (other than a Disqualified Institution) with the consent of Borrower and Administrative Agent; provided, that [***]; and

(iii) during the continuance of an Event of Default, to any Person (including any Disqualified Institution).

(d) Mechanics. The assigning Lender and the assignee thereof shall execute and deliver to Administrative Agent an Assignment Agreement, together with such forms and certificates with respect to tax withholding matters as the assignee under such Assignment Agreement may be required to deliver to Administrative Agent pursuant to Section 2.15(d).

(e) Notice of Assignment. Upon its receipt and acceptance of a duly executed and completed Assignment Agreement, any forms or certificates required by this Agreement in connection therewith, Administrative Agent shall record the information contained in such Assignment Agreement in the Register, shall give prompt notice thereof to Borrower and shall maintain a copy of such Assignment Agreement.

(f) Representations and Warranties of Assignee. Each Lender, upon execution and delivery hereof or upon executing and delivering an Assignment Agreement, as the case may be, represents and warrants as of the Closing Date or as of the applicable Effective Date (as defined in the applicable Assignment Agreement) that (i) it is an Eligible Assignee; (ii) it has experience and expertise in the making of or investing in commitments or loans such as the applicable Term Loan Commitments or Loans, as the case may be; and (iii) it will make or invest in, as the case may be, its Term Loan Commitments or Loans for its own account in the ordinary course of its business and without a view to distribution of such Term Loan Commitments or Loans within the meaning of the Securities Act or the Exchange Act or other federal securities laws.

(g) Effect of Assignment. Subject to the terms and conditions of this Section 10.6, as of the later (i) of the “Effective Date” specified in the applicable Assignment Agreement or (ii) the date such assignment is recorded in the Register: (A) the assignee thereunder shall have the rights and obligations of a “Lender” hereunder to the extent such rights and obligations hereunder have been assigned to it pursuant to such Assignment Agreement and shall thereafter be a party hereto and a “Lender” for all purposes hereof; (B) the assigning Lender thereunder shall, to the extent that rights and obligations hereunder have been assigned thereby pursuant to such Assignment Agreement, relinquish its rights (other than any rights that survive the termination hereof under Section 10.8) and be released from its obligations hereunder (and, in the case of an Assignment Agreement covering all or the remaining portion of an assigning Lender’s rights and obligations hereunder, such Lender shall cease to be a party hereto; provided, anything contained in any of the Loan Documents to the contrary notwithstanding, such assigning Lender shall continue to be entitled to the benefit of all indemnities hereunder as specified herein with respect to matters arising out of the prior involvement of such assigning Lender as a Lender hereunder); (C) the Commitments shall be modified to reflect the Commitment of such assignee and any Commitment of such assigning Lender, if any; and (D) if any such assignment occurs after the issuance of any Note hereunder, the assigning Lender shall, upon the effectiveness of such assignment or as promptly thereafter as practicable, surrender its applicable Notes to Administrative Agent for cancellation, and thereupon Borrower shall issue and deliver new Notes, if so requested by the assignee or assigning Lender, to such assignee or to such assigning Lender, with appropriate insertions, to reflect the new Commitments or outstanding Loans of the assignee or the assigning Lender.

(h) Participations.

(i) Each Lender shall have the right at any time to sell one or more participations to any Person (other than Borrower, any of its Subsidiaries or any of its Affiliates) in all or any part of its Commitments, Loans or in any other Obligation. The holder of any such participation, other than an Affiliate of the Lender granting such participation, shall not be entitled to require such Lender to take or omit to take any action hereunder except with respect to any amendment, modification or waiver that would (i) extend the final scheduled maturity of any Term Loan or Note in which such participant is participating, or reduce the rate or extend the time of payment of interest or fees thereon (except in connection with a waiver of applicability of any post default increase in interest rates) or reduce the principal amount thereof, or increase the amount of the participant’s participation over the amount thereof then in effect (it being understood that a waiver of any Default or Event of Default or of a mandatory reduction in the Commitment shall not constitute a change in the terms of such participation, and that an increase in any Term Loan Commitment or Loan shall be permitted without the consent of any participant if the participant’s participation is not increased as a result thereof), (ii) consent to the assignment or transfer by any Loan Party of any of its rights and obligations under this Agreement, or (iii) release all or substantially all of the Collateral under the Collateral Documents or all or substantially all of the Guarantors from the Guaranty (in each case, except as expressly provided in the Loan Documents) supporting the Loans hereunder in which such participant is participating. Borrower agrees that each participant shall be entitled to the benefits of Sections 2.14, 2.15 and 2.19(c), subject to the requirements and limitations of such Sections (it being understood that the documentation required under Section 2.15(d) shall be delivered solely to the participating Lender) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 10.6(c); provided, a participant shall not be entitled to receive any greater payment under Section 2.15, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation. To the extent permitted by law, each participant also shall be entitled to the benefits of Section 10.4 as though it were a Lender, provided such participant shall be subject to Section 2.13 as though it were a Lender.

(ii) In the event that any Lender sells participations in its Commitments, Loans or in any other Obligation hereunder, such Lender shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of all participants in the Commitments, Loans or Obligations held by it and the principal amount (and stated interest thereon) of the portion of such Commitments, Loans or Obligations that are the subject of the participation (the "Participant Register"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under the Internal Revenue Code or Treasury Regulations, including without limitation Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. A Commitment, Loan or Obligation hereunder may be participated in whole or in part only by registration of such participation on the Participant Register (and each Note shall expressly so provide). The Participant Register shall be available for inspection by Borrower at any reasonable time and from time to time upon reasonable prior notice. For the avoidance of doubt, Administrative Agent (in its capacity as administrative agent) shall not have any responsibility for maintaining a Participant Register. The parties intend that any interest in or with respect to the Loans under this Agreement be treated as being issued and maintained in "registered form" within the meaning of Sections 163(f), 871(h)(2), and 881(c)(2) of the Internal Revenue Code and any regulations thereunder (and any successor provisions), including without limitation under United States Treasury Regulations Section 5f.103-1(c) and Proposed Regulations Section 1.163-5 (and any successor provisions).

(i) Certain Other Assignments. In addition to any other assignment permitted pursuant to this Section 10.6, any Lender or Administrative Agent may assign, pledge or grant a security interest in, all or any portion of its Loans, the other Obligations owed by or to such Lender, and its Notes, if any, to secure obligations of such Lender or Administrative Agent or any of its Affiliates to any Person providing any loan, letter of credit or other extension of credit or financial arrangement to or for the account of such Lender or Administrative Agent or any of its Affiliates and any agent, trustee or representative of such Person (without the consent of, or notice to, or any other action by, any other party hereto), including, without limitation, any Federal Reserve Bank as collateral security pursuant to Regulation A of the Board of Governors of the Federal Reserve System and any operating circular issued by such Federal Reserve Bank; provided, no Lender or Administrative Agent, as between Borrower and such Lender or Administrative Agent, shall be relieved of any of its obligations hereunder as a result of any such assignment and pledge; provided further, in no event shall such Person, agent, trustee or representative of such Person or the applicable Federal Reserve Bank be considered to be a "Lender" or "Agent" or be entitled to require the assigning Lender or Administrative Agent to take or omit to take any action hereunder.

Section 10.7 Independence of Covenants. All covenants hereunder shall be given independent effect so that if a particular action or condition is not permitted by any of such covenants, the fact that it would be permitted by an exception to, or would otherwise be within the limitations of, another covenant shall not avoid the occurrence of a Default or an Event of Default if such action is taken or condition exists.

Section 10.8 Survival of Representations, Warranties and Agreements. All representations, warranties and agreements made herein shall survive the execution and delivery hereof and the making of any Credit Extension. Notwithstanding anything herein or implied by law to the contrary, the agreements of each Loan Party set forth in Sections 2.14, 2.15, 2.19(c), 10.2, 10.3, 10.4, and 10.10 and the agreements of Lenders set forth in Section 2.13, 9.3(b) and 9.6 shall survive the payment of the Term Loans and the termination hereof.

Section 10.9 No Waiver; Remedies Cumulative. No failure or delay on the part of Administrative Agent or any Lender in the exercise of any power, right or privilege hereunder or under any other Loan Document shall impair such power, right or privilege or be construed to be a waiver of any default or acquiescence therein, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other power, right or privilege. The rights, powers and remedies given to Administrative Agent and each Lender hereby are cumulative and shall be in addition to and independent of all rights, powers and remedies existing by virtue of any statute or rule of law or in any of the other Loan Documents. Any forbearance or failure to exercise, and any delay in exercising, any right, power or remedy hereunder shall not impair any such right, power or remedy or be construed to be a waiver thereof, nor shall it preclude the further exercise of any such right, power or remedy.

Section 10.10 Marshalling; Payments Set Aside. Neither Administrative Agent nor any Lender shall be under any obligation to marshal any assets in favor of any Loan Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Loan Party makes a payment or payments to Administrative Agent or Lenders (or to Administrative Agent, on behalf of Lenders), or Administrative Agent or Lenders enforce any security interests or exercise their rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

Section 10.11 Severability. In case any provision in or obligation hereunder or any Note or other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

Section 10.12 Obligations Several; Independent Nature of Lenders' Rights. The obligations of Lenders hereunder are several and no Lender shall be responsible for the obligations or Commitment of any other Lender hereunder. Nothing contained herein or in any other Loan Document, and no action taken by Lenders pursuant hereto or thereto, shall be deemed to constitute Lenders as a partnership, an association, a joint venture or any other kind of entity. The amounts payable at any time hereunder to each Lender shall be a separate and independent debt, and, subject to Section 9.8, each Lender shall be entitled to protect and enforce its rights arising under this Agreement and the other Loan Documents and it shall not be necessary for any other Lender to be joined as an additional party in any proceeding for such purpose.

Section 10.13 [Reserved].

Section 10.14 Original Issue Discount. For purposes of Sections 1272, 1273 and 1275 of the Internal Revenue Code, each Term Loan is being issued with original issue discount; please contact the Borrower as indicated on Appendix B to obtain information regarding the issue date, issue price, the amount of original issue discount and the yield to maturity.

Section 10.15 Headings. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

Section 10.16 APPLICABLE LAW. THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED IN THE STATE OF NEW YORK.

Section 10.17 CONSENT TO JURISDICTION.

(a) ALL JUDICIAL PROCEEDINGS BROUGHT AGAINST ANY PARTY HERETO ARISING OUT OF OR RELATING HERETO OR ANY OTHER LOAN DOCUMENT, OR ANY OF THE OBLIGATIONS, MAY BE BROUGHT IN ANY STATE OR FEDERAL COURT OF COMPETENT JURISDICTION IN THE STATE, COUNTY AND CITY OF NEW YORK. BY EXECUTING AND DELIVERING THIS AGREEMENT, EACH PARTY HERETO, FOR ITSELF AND IN CONNECTION WITH ITS PROPERTIES, IRREVOCABLY (I) ACCEPTS GENERALLY AND UNCONDITIONALLY THE NON-EXCLUSIVE JURISDICTION AND VENUE OF SUCH COURTS; (II) WAIVES ANY DEFENSE OF FORUM NON CONVENIENS; (III) AGREES THAT SERVICE OF ALL PROCESS IN ANY SUCH PROCEEDING IN ANY SUCH COURT MAY BE MADE BY REGISTERED OR CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO THE APPLICABLE LOAN PARTY AT ITS ADDRESS PROVIDED IN ACCORDANCE WITH SECTION 10.1 IS SUFFICIENT TO CONFER PERSONAL JURISDICTION OVER THE APPLICABLE LOAN PARTY IN ANY SUCH PROCEEDING IN ANY SUCH COURT, AND OTHERWISE CONSTITUTES EFFECTIVE AND BINDING SERVICE IN EVERY RESPECT; AND (IV) AGREES THAT ADMINISTRATIVE AGENT AND LENDERS RETAIN THE RIGHT TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW OR TO BRING PROCEEDINGS AGAINST ANY LOAN PARTY IN THE COURTS OF ANY OTHER JURISDICTION.

(b) EACH PARTY HERETO HEREBY AGREES THAT PROCESS MAY BE SERVED ON IT BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO THE ADDRESSES PERTAINING TO IT AS SPECIFIED IN SECTION 10.1. ANY AND ALL SERVICE OF PROCESS AND ANY OTHER NOTICE IN ANY SUCH ACTION, SUIT OR PROCEEDING SHALL BE EFFECTIVE AGAINST ANY LOAN PARTY IF GIVEN BY REGISTERED OR CERTIFIED MAIL, RETURN RECEIPT REQUESTED, OR BY ANY OTHER MEANS OR MAIL THAT REQUIRES A SIGNED RECEIPT, POSTAGE PREPAID, MAILED AS PROVIDED ABOVE.

Section 10.18 WAIVER OF JURY TRIAL. EACH OF THE PARTIES HERETO HEREBY WAIVES ITS RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING HEREUNDER OR UNDER ANY OF THE OTHER LOAN DOCUMENTS OR ANY DEALINGS BETWEEN THEM RELATING TO THE SUBJECT MATTER OF THIS LOAN TRANSACTION OR THE LENDER/BORROWER RELATIONSHIP THAT IS BEING ESTABLISHED. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. EACH PARTY HERETO ACKNOWLEDGES THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS ALREADY RELIED ON THIS WAIVER IN ENTERING INTO THIS AGREEMENT, AND THAT EACH WILL CONTINUE TO RELY ON THIS WAIVER IN ITS RELATED FUTURE DEALINGS. EACH PARTY HERETO FURTHER WARRANTS AND REPRESENTS THAT IT HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL AND THAT IT KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING (OTHER THAN BY A MUTUAL WRITTEN WAIVER SPECIFICALLY REFERRING TO THIS SECTION 10.18 AND EXECUTED BY EACH OF THE PARTIES HERETO), AND THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS HERETO OR ANY OF THE OTHER LOAN DOCUMENTS OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THE LOANS MADE HEREUNDER. IN THE EVENT OF LITIGATION, THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

Section 10.19 Confidentiality. Administrative Agent and Lender shall hold all non-public information regarding Borrower and its Subsidiaries and their businesses identified as such by Borrower and obtained by such Lender from Borrower or its Subsidiaries confidential, it being understood and agreed by Borrower that, in any event, Administrative Agent or Lender may make (i) disclosures of such information to Affiliates of Administrative Agent or Lender and to their agents, advisors, directors, officers, and shareholders (and to other persons authorized by a Lender or Administrative Agent to organize, present or disseminate such information in connection with disclosures otherwise made in accordance with this Section 10.19), (ii) disclosures of such information reasonably required by any bona fide or potential assignee, transferee or participant in connection with the contemplated assignment, transfer or participation by any such Lender of any Loans or any participations therein, subject to such person entering into a customary confidentiality agreement, (iii) disclosure to any rating agency when required by it, (iv) disclosure to any Lender's financing sources, provided that prior to any disclosure, such financing source is subject to customary confidentiality obligations, (v) disclosures of such information to any actual or potential investors, members, and partners of Administrative Agent any Lender or their Affiliates, provided that prior to any disclosure, such investor or partner is informed of the confidential nature of the information, and (vi) disclosure required or requested in connection with any public filings, whether pursuant to any securities laws or regulations or rules promulgated therefor (including the Investment Company Act of 1940 or otherwise) or representative thereof or by the National Association of Insurance Commissioners (and any successor thereto) or pursuant to legal or judicial process; provided, unless specifically prohibited by applicable law or court order, Administrative Agent and Lender shall make reasonable efforts to notify Borrower of any request by any Governmental Authority or representative thereof (other than any such request in connection with any examination of the financial condition or other routine examination of such Lender by such Governmental Authority) for disclosure of any such non-public information prior to disclosure of such information. Notwithstanding anything to the contrary set forth herein, each party (and each of their respective employees, representatives or other agents) may disclose to any and all persons, without limitations of any kind, the tax treatment and tax structure of the transactions contemplated by this Agreement and all materials of any kind (including opinions and other tax analyses) that are provided to any such party relating to such tax treatment and tax structure. However, any information relating to the tax treatment or tax structure shall remain subject to the confidentiality provisions hereof (and the foregoing sentence shall not apply) to the extent reasonably necessary to enable the parties hereto, their respective Affiliates, and their and their respective Affiliates' directors and employees to comply with applicable securities laws. For this purpose, "tax structure" means any facts relevant to the federal income tax treatment of the transactions contemplated by this Agreement but does not include information relating to the identity of any of the parties hereto or any of their respective Affiliates. Notwithstanding the foregoing, on or after the Closing Date, Administrative Agent and any Lender may, at its own expense, issue news releases and publish "tombstone" advertisements and other announcements relating to this transaction in newspapers, trade journals and other appropriate media (which may include use of logos of one or more of the Loan Parties) (collectively, "Trade Announcements"). No Loan Party shall (i) issue any Trade Announcement or (ii) disclose the name of any Administrative Agent or any Lender except in the case of clause (ii) (A) disclosures required by applicable law, regulation, legal process or the rules of the Securities and Exchange Commission, (B) on a confidential basis to the Borrower's controlled Affiliates and Subsidiaries and the Borrower's and their controlled Affiliates' and Subsidiaries' Board of Directors (or equivalent governing body), employees, representatives and professional advisors, subject, in the case of this clause (B), to such person being subject to customary confidentiality obligations with respect to this Agreement, (C) to the extent such information becomes publicly available other than by reason of improper disclosure in violation of the confidentiality obligations set forth in this Section 10.19, (D) to a Tax authority, to the extent reasonably necessary in connection with the Tax affairs of the Borrower or any of its Affiliates or (E) with the prior approval of Administrative Agent and such Lender. The respective obligations of Administrative Agent and Lender under this Section 10.19 shall survive, to the extent applicable to such Person, for a period of two (2) years after the earliest of (x) the payment in full of the Obligations and the termination of this Agreement, (y) any assignment of its rights and obligations under this Agreement by such Person and (z) the resignation or removal of such Person as an Administrative Agent.

Section 10.20 Usury Savings Clause. Notwithstanding any other provision herein, the aggregate interest rate charged or agreed to be paid with respect to any of the Obligations, including all charges or fees in connection therewith deemed in the nature of interest under applicable law shall not exceed the Highest Lawful Rate. If the rate of interest (determined without regard to the preceding sentence) under this Agreement at any time exceeds the Highest Lawful Rate, the outstanding amount of the Loans made hereunder shall bear interest at the Highest Lawful Rate until the total amount of interest due hereunder equals the amount of interest that would have been due hereunder if the stated rates of interest set forth in this Agreement had at all times been in effect. In addition, if when the Loans made hereunder are repaid in full the total interest due hereunder (taking into account the increase provided for above) is less than the total amount of interest that would have been due hereunder if the stated rates of interest set forth in this Agreement had at all times been in effect, then to the extent permitted by law, Borrower shall pay to Administrative Agent an amount equal to the difference between the amount of interest paid and the amount of interest that would have been paid if the Highest Lawful Rate had at all times been in effect. Notwithstanding the foregoing, it is the intention of Lenders and Borrower to conform strictly to any applicable usury laws. Accordingly, if any Lender contracts for, charges, or receives any consideration that constitutes interest in excess of the Highest Lawful Rate, then any such excess shall be cancelled automatically and, if previously paid, shall at such Lender's option be applied to the outstanding amount of the Loans made hereunder or be refunded to Borrower. In determining whether the interest contracted for, charged, or received by Administrative Agent or a Lender exceeds the Highest Lawful Rate, such Person may, to the extent permitted by applicable law, (a) characterize any payment that is not principal as an expense, fee, or premium rather than interest, (b) exclude voluntary prepayments and the effects thereof, and (c) amortize, prorate, allocate, and spread in equal or unequal parts the total amount of interest, throughout the contemplated term of the Obligations hereunder.

Section 10.21 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument. This Agreement shall become effective upon the execution of a counterpart hereof by each of the parties hereto. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means shall be effective as delivery of a manually executed counterpart of this Agreement. The words "execution," "execute," "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby (including without limitation an Assignment Agreement, amendments, Notices, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

Section 10.22 Effectiveness. This Agreement shall become effective upon the execution of a counterpart hereof by each of the parties hereto and receipt by Borrower and Administrative Agent of written notification of such execution and authorization of delivery thereof.

Section 10.23 PATRIOT Act Notice. Each Lender and Administrative Agent (for itself and not on behalf of any Lender) hereby notifies the Loan Parties that pursuant to the requirements of the PATRIOT Act, it may be required to obtain, verify and record information that identifies each Loan Party, which information includes the name and address of the Loan Parties and other information that will allow such Lender or Administrative Agent, as applicable, to identify the Loan Parties in accordance with the PATRIOT Act or other Anti-Terrorism Laws of the Loan Parties and other information that will allow such Lender or Administrative Agent, as applicable, to identify the Loan Parties in connection with the PATRIOT Act.

Section 10.24 Waiver of Immunity. To the extent that any Loan Party has or hereafter may acquire (or may be attributed, whether or not claimed) any immunity (sovereign or otherwise) from any legal action, suit or proceeding, from jurisdiction of any court or from set-off or any legal process (whether service of process or notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) with respect to itself or any of its property, such Loan Party hereby irrevocably waives and agrees not to plead or claim, to the fullest extent permitted by law, such immunity in respect of (a) its obligations under the Loan Documents, (b) any legal proceedings to enforce such obligations and (c) any legal proceedings to enforce any judgment rendered in any proceedings to enforce such obligations. Each Loan Party hereby agrees that the waivers set forth in this Section 10.23 shall be to the fullest extent permitted under the Foreign Sovereign Immunities Act and are intended to be irrevocable for purposes of the Foreign Sovereign Immunities Act.

Section 10.25 Service of Process. Each Loan Party that is organized outside of the United States hereby appoints Borrower as its agent for the purpose of accepting service of any process in the United States with respect to any Loan Document and the transactions contemplated thereby.

Section 10.26 Acknowledgement and Consent to Bail-In of Affected Financial Institutions. Notwithstanding anything to the contrary in any Loan Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Affected Financial Institution arising under any Loan Document, to the extent such liability is unsecured, may be subject to the write-down and conversion powers of the applicable Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by:

(a) the application of any Write-Down and Conversion Powers by the applicable Resolution Authority to any such liabilities arising hereunder that may be payable to it by any party hereto that is an Affected Financial Institution; and

(b) the effects of any Bail-in Action on any such liability, including, if applicable:

(i) a reduction in full or in part or cancellation of any such liability;

(ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such Affected Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Loan Document; or

(iii) the variation of the terms of such liability in connection with the exercise of the write-down and conversion powers of the applicable Resolution Authority.

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**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 9, 2024

/s/ Michael S. Weiss

Michael S. Weiss

Chairman, Chief Executive Officer and President

**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 9, 2024

/s/ Sean A. Power

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

STATEMENT OF CHIEF EXECUTIVE OFFICER OF**TG THERAPEUTICS, INC.****PURSUANT TO 18 U.S.C. SECTION 1350,****AS ADOPTED PURSUANT TO****SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chairman, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2024

/s/ Michael S. Weiss

Michael S. Weiss

Chairman, Chief Executive Officer and President

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, 2024 as filed with the Securities and Exchange Commission (the “Report”), I, Sean A. Power, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2024

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer