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, 2023

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number: 001-39101

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**47-4639500**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

(484) 395-2440
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.01	**BXRX**	**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 Section13(a) of the Exchange Act. ☒

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

As of August 8, 2023, there were 6,968,796 shares of common stock, par value $0.01 per share, outstanding.

TABLE OF CONTENTS
Index

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would," "could," "should," "potential," "seek," "evaluate," "pursue," "continue," "design," "impact," "affect," "forecast," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

These forward-looking statements in this Quarterly Report include, among other things, statements about:

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to continue as a going concern for the next twelve months;
- whether our cash resources will be sufficient to fund our continuing operations;
- our ability to operate under significant indebtedness;
- our ability to regain compliance with the listing requirements of the Nasdaq Capital Market;
- our ability to obtain regulatory approval for any product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved product candidates;
- our ability to successfully market, commercialize and achieve broad market acceptance for any of our product candidates once approved;
- our ability and that of our third-party manufacturers to successfully transfer or scale-up our clinical and commercial manufacturing processes for our product candidates;
- the results, timing and outcome of our clinical trials of our product candidates, and any future clinical trials and preclinical studies;
- our ability to source materials needed for our product candidates, optimize formulations for stability and other characteristics;
- our relationships with licensors, collaborators, other third parties and our employees;
- our ability to successfully integrate the operations of our recent acquisition, TeraImmune, Inc., or TeraImmune, and realize anticipated benefits of the acquisition of TeraImmune;
- our ability to obtain shareholder approval of the conversion of our Series X Non-Voting Convertible Preferred Stock, or Series X Preferred Stock, and the required cash payment of the then-current fair value of the Series X Preferred Stock if such approval is not obtained;
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the separation from Societal CDMO's acute care business and transfer of such assets to us, or the Separation, and changes in the tax laws;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- the performance of third-parties upon which we depend, including third-parties involved with clinical trial execution, and third-party suppliers, manufacturers, supply chain and logistics providers;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- our ability to obtain regulatory exclusivity periods for our products post approval, or our ability to obtain orphan drug status for certain of our product candidates;
- our ability to develop relationships with potential collaborators and development partners;
- our ability to defend any material litigation filed against us and avoid liabilities resulting from any material litigation;

- our ability to recruit or retain key scientific, technical, and management personnel or to retain our executive officers;
- our ability to raise future financing for continued development of our business and our product candidates and to meet any required debt payments, and any milestone payments we may owe;
- the volatility of capital markets and other macroeconomic factors, including inflationary pressures, banking instability issues, geopolitical tensions or the outbreak of hostilities or war;
- our ability to operate under leverage and comply with associated lending covenants; to pay existing required interest and principal amortization payments when due; and/or to obtain acceptable refinancing alternatives; and
- our expectations regarding continuing effects of the COVID-19 pandemic, including manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, and the overall impact of the COVID-19 pandemic on our business, financial condition and results of operations.

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the "Risk Factors" included in Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023, or the 2022 Annual Report, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Quarterly Report and you should not place undue reliance on any forward-looking statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BAUDAX BIO, INC.
Consolidated Balance Sheets
(Unaudited)

(amounts in thousands, except share and per share data)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,416	$ 5,259
Prepaid expenses and other current assets	444	303
Current assets of discontinued operation	—	785
Total current assets	1,860	6,347
Property and equipment, net	3,781	9
Right-of-use asset, net	2,939	854
Intangible asset, net	3,500	—
Goodwill	9,236	2,127
Non-current assets of discontinued operation	—	695
Total assets	$ 21,316	$ 10,032
Liabilities, Non-Voting Convertible Preferred Stock and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,828	$ 3,198
Accrued expenses and other current liabilities	2,648	2,133
Current portion of long-term debt, net	4,861	5,600
Current portion of operating lease liability	614	231
Contingent consideration	260	—
Convertible bond payable	1,000	—
Derivative instrument	5,246	—
Current liabilities of discontinued operation	—	10,298
Total current liabilities	20,457	21,460
Long-term debt, net	—	1,519
Long-term operating lease liability	2,296	585
Deferred tax liability	202	—
Other long-term liabilities	—	13
Non-current liabilities of discontinued operation	—	10,697
Total liabilities	22,955	34,274
Commitments and contingencies (Note 12)		
Mezzanine equity:		
Series X non-voting convertible preferred stock, $0.01 par value, Authorized, 27,090 shares; issued and outstanding 20,066 shares at June 30, 2023	9,040	—
Shareholders' deficit:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 6,961,867 shares at June 30, 2023 and 1,623,913 shares at December 31, 2022	70	16
Additional paid-in capital	176,126	166,646
Accumulated deficit	(186,875)	(190,904)
Total shareholders' deficit	(10,679)	(24,242)
Total liabilities, non-voting convertible preferred stock and shareholders' deficit	$ 21,316	$ 10,032

See accompanying notes to unaudited consolidated financial statements.

BAUDAX BIO, INC.
Consolidated Statements of Operations
(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended June 30, 2023	2022	For the Six Months Ended June 30, 2023	2022
Operating expenses:				
Research and development	$ 1,779	$ 879	$ 4,696	$ 1,573
General and administrative	2,254	2,898	4,025	9,832
Change in fair value of warrants and derivatives	2,870	(1)	2,870	(6)
Change in contingent consideration valuation	142	—	142	—
Total operating expenses	7,045	3,776	11,733	11,399
Operating loss from continuing operations	(7,045)	(3,776)	(11,733)	(11,399)
Other expense:				
Other expense, net	(256)	(569)	(2,954)	(1,140)
Net loss from continuing operations	$ (7,301)	$ (4,345)	$ (14,687)	$ (12,539)
Income (loss) on discontinued operation	(74)	(3,186)	18,716	(7,801)
Net income (loss)	$ (7,375)	$ (7,531)	$ 4,029	$ (20,340)
Per share information:				
Net loss per share from continuing operations, basic and diluted	$ (1.49)	$ (24.20)	$ (4.08)	$ (89.40)
Net income (loss) per share from discontinued operation, basic and diluted	$ (0.02)	$ (17.75)	$ 5.20	$ (55.62)
Net income (loss) per share, basic and diluted	$ (1.51)	$ (41.95)	$ 1.12	$ (145.03)
Weighted average common shares outstanding, basic and diluted	4,885,215	179,541	3,601,877	140,251

See accompanying notes to unaudited consolidated financial statements.

BAUDAX BIO, INC.
Consolidated Statements of Non-voting Convertible Preferred Stock and Shareholders' Deficit
(Unaudited)

For the Six Months Ended June 30, 2023

	Series X Convertible Preferred Stock		Common Stock		Additional paid-in	Accumulated	
(amounts in thousands, except share data)	**Shares**	**Amount**	**Shares**	**Amount**	**capital**	**Deficit**	**Total**
Balance, December 31, 2022	—	$ —	1,623,913	$ 16	$ 166,646	$ (190,904)	$ (24,242)
Stock-based compensation expense	—	—	—	—	194	—	194
Issuance of common stock and warrants for public offering, net	—	—	—	—	(55)	—	(55)
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	2	—	—	—	—
Exercise of warrants	—	—	961,787	10	4,318	—	4,328
Issuance of warrants for MAM debt amendment	—	—	—	—	1,058	—	1,058
Net income	—	—	—	—	—	11,404	11,404
Balance, March 31, 2023	—	$ —	2,585,702	$ 26	$ 172,161	$ (179,500)	$ (7,313)
Stock-based compensation expense	—	—	—	—	208	—	208
Issuance of common stock and warrants for public offering, net	—	—	3,478,262	35	3,222	—	3,257
Issuance of Series X convertible preferred stock upon acquisition of TeraImmune	20,066	9,040	—	—	—	—	—
Issuance of common stock upon acquisition of TeraImmune	—	—	897,903	9	535	—	544
Net loss	—	—	—	—	—	(7,375)	(7,375)
Balance, June 30, 2023	20,066	$ 9,040	6,961,867	$ 70	$ 176,126	$ (186,875)	$ (10,679)

See accompanying notes to unaudited consolidated financial statements.

BAUDAX BIO, INC.
Consolidated Statements of Shareholders' (Deficit) Equity
(Unaudited)

For the Six Months Ended June 30, 2022

	Preferred Stock		Common Stock		Additional paid-in	Accumulated	
(amounts in thousands, except share data)	**Shares**	**Amount**	**Shares**	**Amount**	**capital**	**Deficit**	**Total**
Balance, December 31, 2021	8,289	$ —	70,181	$ 1	$ 145,314	$ (132,089)	$ 13,226
Stock-based compensation expense	—	—	—	—	521	—	521
Issuance of common stock and warrants for registered direct offerings, net	—	—	—	—	(13)	—	(13)
Issuance of common stock and warrants for public offering, net	—	—	87,719	1	8,817	—	8,818
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	56	—	—	—	—
Conversion of preferred stock	(8,289)	—	2,368	—	—	—	—
Net loss	—	—	—	—	—	(12,809)	(12,809)
Balance, March 31, 2022	—	$ —	160,324	$ 2	$ 154,639	$ (144,898)	$ 9,743
Stock-based compensation expense	—	—	—	—	325	—	325
Issuance of common stock and warrants for registered direct offerings, net	—	—	41,152	—	1,720	—	1,720
Issuance of common stock and warrants for public offering, net	—	—	—	—	(28)	—	(28)
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	245	—	—	—	—
Net loss	—	—	—	—	—	(7,531)	(7,531)
Balance, June 30, 2022	—	$ —	201,721	$ 2	$ 156,656	$ (152,429)	$ 4,229

See accompanying notes to unaudited consolidated financial statements.

BAUDAX BIO, INC.
Consolidated Statements of Cash Flows
(Unaudited)

(amounts in thousands)	For the Six Months Ended June 30, 2023	2022
Cash flows from operating activities:		
Net income (loss)	$ 4,029	$ (20,340)
(Income) loss on discontinued operation	(18,716)	7,801
Adjustments to reconcile net income (loss) from continuing operations to net cash used in operating activities from continuing operations:		
Stock-based compensation	389	786
Non-cash interest expense	291	449
Depreciation expense	4	29
Non-cash loss on retirement of fixed assets	5	8
Loss on extinguishment of debt	2,196	—
Change in fair value of warrants and derivatives	2,870	(6)
Right-of-use asset	49	66
Change in contingent consideration valuation	142	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(78)	558
Accounts payable, accrued expenses and other liabilities	1,550	751
Operating lease liability	(41)	(108)
Net cash used in operating activities, continuing operations	(7,310)	(10,006)
Cash flows from investing activities:		
Cash acquired in acquisition of TeraImmune	142	—
Net cash provided by investing activities, continuing operations	142	—
Cash flows from financing activities:		
Payment of deferred financing costs	(197)	—
Proceeds from public offering, net of transaction costs	3,494	8,925
Proceeds from registered direct offerings, net of transaction costs	—	1,816
Payments on long-term debt	(3,500)	(278)
Proceeds from warrant exercises	4,328	—
Payments of withholdings on shares withheld for income taxes	—	(2)
Net cash provided by financing activities, continuing operations	4,125	10,461
Net (decrease) increase in cash and cash equivalents from continuing operations	(3,043)	455
Discontinued operation:		
Cash flows used in operating activities	(800)	(10,116)
Cash flows used in investing activities	—	(20)
Cash flows used in financing activities	—	(1,000)
Net decrease in cash and cash equivalents from discontinued operations	(800)	(11,136)
Cash and cash equivalents, beginning of period	5,259	15,891
Cash and cash equivalents, end of period	$ 1,416	$ 5,210
Supplemental disclosure of cash flow information:		
Acquisition of TeraImmune through issuance of Series X convertible preferred stock and common stock, net of cash acquired	$ 9,560	$ —
Offering costs included in accounts payable and accrued expenses	$ 950	$ 213

See accompanying notes to unaudited consolidated financial statements.

(1) Background

Business

Baudax Bio, Inc. ("Baudax Bio" or the "Company") is a biotechnology company focused on developing T cell receptor ("TCR") therapies utilizing human regulatory T cells ("Tregs"), as well as a portfolio of clinical stage Neuromuscular Blocking Agents ("NMBs") and an associated reversal agent. The Company's TCR Treg programs primarily focus on immune modulating therapies for orphan diseases or complications associated with such diseases, as well as the treatment of autoimmune disorders. The Company believes that its TCR Treg programs have the potential to provide valuable therapeutic options to patients suffering from diseases for which there are limited treatment options and significant unmet need, as well as to prescribers and payers in these markets.

On June 29, 2023, the Company acquired TeraImmune, Inc. ("TeraImmune"), a Delaware corporation (the "Acquisition"). TeraImmune was a privately-held biotechnology company focused on discovery and development of novel Treg-based cell therapies for autoimmune diseases. TeraImmune's proprietary and patented technology platforms include a method for expansion of the Treg without losing its function and stability, as well as a method to target specific receptors including TCRs, Chimeric Antigen Receptors ("CARs") and B cell Antigen Receptors ("BARs"). TeraImmune has also in-licensed through an exclusive, sublicensable, royalty-bearing license, a patent family covering methods of producing T cell populations enriched for regulatory T cells and cell culture compositions from U.S. Department of Health and Human Services, as represented by National Institute of Allergy and Infectious Diseases of the National Institutes of Health. In addition, TeraImmune has developed Treg manufacturing procedures in accordance with regulatory guidance from the U.S. Food and Drug Administration ("FDA"). In June 2022, TeraImmune's Investigational New Drug ("IND") application to commence clinical trials of a Factor VIII ("FVIII") TCR-Treg treatment for Hemophilia A with inhibitors was cleared by the FDA. For additional information on the Acquisition, see Note 5.

The Company also holds exclusive global rights to two new molecular entities, which are centrally acting neuromuscular blocking agents ("NMBs"), BX1000, an intermediate duration of action NMB that recently completed a successful Phase II clinical trial, and BX2000, an ultra-short acting NMB currently undergoing a Phase I clinical trial. A proprietary blockade reversal agent, BX3000, is currently being evaluated in preclinical studies intended to support an IND filing in 2023. BX3000 is an agent that is expected to rapidly reverse BX1000 and BX2000 blockade. All three agents are licensed from Cornell University. The Company believes these agents, when an NMB and BX3000 are administered in succession, allow for a rapid onset of centrally acting neuromuscular blockade, followed by a rapid reversal of the neuromuscular blockade with BX3000. These novel agents have the potential to meaningfully reduce time to onset and reversal of blockade and improve the reliability of onset and offset of neuromuscular blockade. This can potentially reduce time in operating rooms or post operative suites (PACU), resulting in potential clinical and cost advantages, as well as valuable cost savings for hospitals and ambulatory surgical centers and has the potential for an improved clinical profile in terms of safety.

In mid-2020, the Company launched its first commercial product, ANJESO, in the United States. ANJESO was the first and only 24-hour, intravenous, or IV, analgesia agent. ANJESO is a cyclooxygenase-2 ("COX-2") preferential, non-steroidal anti-inflammatory drug ("NSAID") for the management of moderate to severe pain, which could be administered alone or in combination with other non-NSAID analgesics. The Company discontinued commercial sales of ANJESO in December 2022 and further withdrew its New Drug Application ("NDA") related to ANJESO in late March 2023. See Note 4 for discussion on the discontinued operation related to our ANJESO commercial business.

The Company has determined that it operates in a single segment involved in innovative products for hospital and related settings.

Reverse Stock Splits

On February 16, 2022, the Company effected a reverse split of shares of the Company's common stock on a 1-for-35 basis (the "Reverse Stock Split"). On December 1, 2022, the Company effected a second reverse split of shares of the Company's common stock on a 1-for-40 basis (the "December Reverse Stock Split"). All issued and outstanding shares of common stock, warrants, common stock options, and unvested restricted stock units and the related per share amounts contained in the financial statements have been retroactively adjusted to reflect these reverse stock splits for all periods presented. The par value and authorized shares of common stock were not adjusted as a result of the reverse stock splits. Additionally, the authorized, issued and outstanding shares of preferred stock and their related per share amount, other than the conversion price per share, was not adjusted as a result of the reverse stock splits.

(2) Development Activity Risks, Liquidity and Going Concern

The Company has incurred operating losses since inception and has negative cash flows, working capital and equity, including an accumulated deficit of $186,875, as of June 30, 2023.

Additionally, TeraImmune failed to pay its Convertible Bond Agreement, dated March 22, 2022, with EoFlow Co., Ltd. (the ‘‘5% Convertible Term Loan’’), on the stated maturity date of November 30, 2022. The Company is offering conversion of the notes with an outstanding balance, including accrued interest, of $1,239 at June 30, 2023, into shares of the Company's common stock or by providing the noteholders with a repayment plan. This debt was part of the liabilities assumed by the Company in connection with the acquisition of TeraImmune (see Notes 5 and 11).

The Company has raised funds from debt and equity transactions and will be required to raise additional funds to continue to operate as a standalone entity. In order to fund development activities, and clinical and pre-clinical testing, the Company will require significant additional funding. The Company could delay clinical trial activity or reduce funding of specific programs in order to reduce cash needs. Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, future commercialization, or expansion activities. The Company may raise such funds, if available, through debt financings, bank or other loans, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company’s growth plans and its financial condition or results of operations and ability to continue as a going concern. Additional debt or equity financing, if available, may be dilutive to holders of the Company’s common stock and may involve significant cash payment obligations and covenants that restrict the Company’s ability to operate its business.

The Company's management assesses the Company’s ability to continue as a going concern for one year after the date the consolidated financial statements are issued. Based on the Company’s available cash and cash equivalents as of June 30, 2023, management has concluded that substantial doubt exists about the Company’s ability to continue as a going concern for one year from the date these financial statements are issued. The Company expects to seek additional funding to sustain its future operations and while the Company has successfully raised capital in the past, the ability to raise capital in future periods is not assured. The Company is not expected to be able to maintain its minimum liquidity covenant over the next twelve months without additional inflows of funds or capital financing. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”), for interim financial information and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by U.S. GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company’s results for the interim periods. The Consolidated Balance Sheet as of December 31, 2022 has been derived from audited financial statements. Operating results for the three and six months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2023. The Company’s consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2022 included in the Company’s Form 10-K.

(b) Use of Estimates

The preparation of unaudited consolidated financial statements and the notes to the unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Cash and Cash Equivalents

Cash and cash equivalents represent cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired to be cash equivalents. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near to their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to seven years for furniture and office equipment; three years for computer and software; three to seven years for manufacturing equipment; and the shorter of the remaining lease term or useful life for leasehold improvements. Repairs and maintenance costs are expensed as incurred.

(e) Business Combinations

In accordance with Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC"), Topic 805, "Business Combinations," ("ASC 805"), the Company allocates the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make significant estimates and assumptions, in particular with respect to intangible assets. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from management of the acquired companies and expectations of future cash flows. Transaction costs associated with the transaction are expensed as incurred. In-process research and development ("IPR&D"), is the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires the Company to make significant estimates. In a business combination, the Company capitalizes IPR&D as an intangible asset.

(f) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a one-step method for determining impairment.

The one-step quantitative test calculates the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company has one reporting unit.

The Company's intangible asset was acquired through the Acquisition and is classified as an IPR&D asset. Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Consolidated Statements of Operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The impairment test for indefinite-lived intangible assets is a one-step test that compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess.

The Company performs its annual goodwill and indefinite-lived intangible asset impairment tests as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. The Company performed a goodwill impairment test as of June 30, 2023 after identifying indicators of impairment. There was no impairment to goodwill based on the analysis.

(g) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company manages its cash and cash equivalents based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

(h) Research and Development

Research and development costs for the Company's proprietary products candidates are charged to expense as incurred. Research and development expenses consist of internal costs and funds incurred internally or paid to third parties for the provision of services for pre-commercialization and manufacturing scale-up activities, drug development, pre-clinical activities, clinical trials, statistical analysis, report writing and regulatory filing fees and compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development project. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expenses relating to these costs.

Upfront and milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining product technology licenses are charged to research and development expense as acquired in-process research and development ("IPR&D") if the technology licensed has not reached technological feasibility and has no alternative future use.

(i) Stock-Based Awards

Share-based compensation included in the unaudited consolidated financial statements is based upon the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Baudax Bio 2019 Plan") and the TeraImmune 2019 Equity Incentive Plan (the "TeraImmune 2019 Plan"). These plans include grants of stock options, time-based vesting restricted stock units ("RSUs") and performance-based RSUs. The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. The Company accounts for forfeitures as they occur.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses an average of its peer group's volatility in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option. The Company has never declared or paid cash dividends and has no plans to do so in the foreseeable future, therefore the dividend yield is zero.

(j) Redeemable Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally

redeemable preferred shares, including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, and consisting of Series X Non-Voting Convertible Preferred Stock ("Series X Preferred Stock") are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

(k) Equity-method Investment

The Company uses the equity method of accounting for equity investments if the investment provides the ability to exercise significant influence, but not control, over operating and financial policies of the investee. The Company's proportionate share of the net income or loss of these investees is included in our statements of operations. Judgment regarding the level of influence over each equity method investment includes considering key factors such as the Company's ownership interest, legal form of the investee, representation on the board of directors, participation in policy-making decisions and material intra-entity transactions.

The Company's equity-method investment includes its investment in TeraImmune Therapeutics, Co., Ltd., ("TIT"). The carrying value of the Company's investment in TIT is recorded in equity method investments in the consolidated balance sheet and is immaterial as of June 30, 2023.

(l) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized. Because of the Company's history of losses as a standalone entity, a full valuation allowance is recorded against deferred tax assets in all periods presented.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

Under the Tax Reform Act of 1986, as amended (the "Act"), the utilization of a corporation's net operating loss is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company is evaluating whether the Acquisition triggered an ownership change under these rules.

(m) Net Income (Loss) Per Common Share

Net loss per common share is computed using the two-class method required due to the participating nature of the Series A Preferred Stock (as defined and discussed in Note 13(b)) and the Series X Preferred Stock (together, "Preferred Stock"). Except with respect to voting and conversion, the rights of the holders of the Company's common stock and the Company's Series A Preferred Stock and Series X Preferred Stock are identical. Each class of shares has the same rights to dividends. Although the Preferred Stock are participating securities, such securities do not participate in net losses and therefore do not impact the Company's net loss from continuing operations per share calculation as of June 30, 2023.

Basic net loss per common share is determined by dividing net loss attributable to common shareholders by the weighted average common shares outstanding during the period. Diluted net loss per common share is determined using the weighted average common shares outstanding during the period plus the weighted average number of shares of common shares that would be issued assuming exercise or conversion of all potentially dilutive instruments. The Company uses income from continuing operations as the control number in determining whether potential common shares are dilutive or antidilutive. The same number of potential common shares used in computing the diluted per-share amount for income from continuing operations is used in computing all other reported diluted per-share amounts even if those amounts will be antidilutive to their respective basic per-share amounts. Outstanding warrants, common stock options, unvested restricted stock units and

(amounts in thousands, except share and per share data)

convertible redeemable preferred shares are excluded from the calculation of diluted net loss per share when their effect would be anti-dilutive.

For purposes of calculating basic and diluted loss per common share, the denominator includes the weighted average common shares outstanding, the weighted average common stock equivalents for warrants priced at par value, or $0.01, as the underlying common shares will be issued for little cash consideration and the conditions for the issuance of the underlying common shares are met when such warrants are issued, and, with regard to diluted loss per common share, the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

The following table sets forth the computation of basic and diluted income (loss) per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Basic and Diluted Income (Loss) Per Share				
Net loss from continuing operations	$ (7,301)	$ (4,345)	$ (14,687)	$ (12,539)
Net income (loss) from discontinued operation	$ (74)	$ (3,186)	$ 18,716	$ (7,801)
Net income (loss)	$ (7,375)	$ (7,531)	$ 4,029	$ (20,340)
Net loss per share from continuing operations	$ (1.49)	$ (24.20)	$ (4.08)	$ (89.40)
Net income (loss) per share from discontinued operation	$ (0.02)	$ (17.75)	$ 5.20	$ (55.62)
Net income (loss) per share of common stock, basic and diluted	$ (1.51)	$ (41.95)	$ 1.12	$ (145.03)
Weighted average common shares outstanding, basic and diluted	4,885,215	179,541	3,601,877	140,251

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Options and restricted stock units outstanding	977,491	15,239	977,491	15,239
Warrants	9,838,018	173,750	9,838,018	173,750
Series X Preferred Stock	20,066,208	—	20,066,208	—

Amounts in the table above reflect the common stock equivalents of the noted instruments.

(n) Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that the Company has or will adopt as of a specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have a material impact on the Company's present or future consolidated financials.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*," or ASU 2016-13. ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires consideration of a range of reasonable information to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including those interim periods

(amounts in thousands, except share and per share data)

within those fiscal years. The Company adopted this guidance as of January 1, 2023 and noted no impact to the Company or its disclosures.

4) Discontinued Operations

In March 2023, the Company entered into an Asset Transfer Agreement with Alkermes Pharma Ireland Limited ("Alkermes") (the "Transfer Agreement"). Under the terms of the Transfer Agreement, the Company transferred the rights to certain patents, trademarks, equipment, data and other rights related to ANJESO (the "Assets") to Alkermes. The Company also withdrew the New Drug Application ("NDA") related to ANJESO and agreed, if elected by Alkermes at a later date, to transfer such withdrawn NDA to Alkermes at no additional cost.

Additionally, under the Transfer Agreement, the Company granted Alkermes a non-exclusive, perpetual and irrevocable, royalty-free and fully paid-up worldwide license, to the additional intellectual property owned by the Company necessary to or useful to exploit ANJESO. In consideration of the transfer of the Assets, the parties agreed to the termination of (i) the Purchase and Sale Agreement, dated March 7, 2015 by and among Alkermes, the Company and the other parties thereto (as amended, the "PSA"), (ii) the Asset Transfer and License Agreement, dated April 10, 2015 by and among Alkermes, the Company and the other parties thereto (as amended, the "ATLA"); and (iii) the Development, Manufacturing and Supply Agreement, dated as of July 10, 2015 by and between the Company and Alkermes (as amended, the "Manufacturing Agreement") between the parties related to ANJESO (the PSA, ATLA and Manufacturing Agreement, collectively, the "ANJESO Agreements"). In connection with the termination of the ANJESO Agreements, no further payments of any kind pursuant to the ANJESO Agreements are payable by the Company to Alkermes.

The accounting requirements for reporting the abandonment of ANJESO as a discontinued operation were met when the agreements with Alkermes were executed. Accordingly, the accompanying consolidated financial statements for all periods presented reflect this business as a discontinued operation.

The historical consolidated balance sheet and statements of operations of the Company and the related notes to the consolidated financial statements have been presented as discontinued operations in the consolidated financial statements and prior periods have been recast. Discontinued operations include results of the Company's commercial business except for certain corporate overhead costs, which are included in continuing operations.

There were no assets or liabilities of discontinued operations as of June 30, 2023. The following table shows amounts included in assets and liabilities of discontinued operations, respectively, on the Company's Consolidated Balance Sheet at December 31, 2022:

	December 31, 2022
Current assets of discontinued operation:	
Accounts receivable, net	$ 336
Prepaid expenses and other current assets	449
Total current assets of discontinued operation	785
Non-current assets of discontinued operation:	
Property and equipment, net	695
Total non-current assets of discontinued operation	695
Total assets of discontinued operation	$ 1,480
Current liabilities of discontinued operation:	
Accounts payable	$ 730
Accrued expenses and other current liabilities	365
Current portion of contingent consideration	9,203
Total current liabilities of discontinued operation	10,298
Non-current liabilities of discontinued operation:	
Long-term portion of contingent consideration	10,697
Total non-current liabilities of discontinued operation	10,697
Total liabilities of discontinued operation	$ 20,995

(amounts in thousands, except share and per share data)

The results of operations from discontinued operations for the three and six months ended June 30, 2023 and 2022, have been reflected as discontinued operations in the consolidated statements of operations and consist of the following:

	For the Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue, net	$ 30	$ 300	$ 16	$ 722
Operating expenses:				
Cost of sales	104	361	509	1,009
Research and development	—	33	—	632
Selling, general and administrative	—	1,131	—	8,387
Amortization of intangible assets	—	644	—	1,288
Change in contingent consideration valuation	—	1,327	(19,900)	(2,476)
Loss on impairment of property and equipment	—	—	485	—
Total operating expenses	104	3,496	(18,906)	8,840
Operating gain (loss) from discontinued operation	(74)	(3,196)	18,922	(8,118)
Other expense:				
Other expense, net	—	10	(206)	317
Net income (loss) from discontinued operation	$ (74)	$ (3,186)	$ 18,716	$ (7,801)

The Company sold ANJESO in the U.S. through a single third-party logistics provider (“3PL”), which took title to and control of the goods, and was considered the customer. The Company recognized revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtains control of the product. The transaction price that was recognized as revenue for products includes an estimate of variable consideration for reserves, which result from discounts, returns, chargebacks, rebates, and other allowances that were offered within contracts between the Company and end-user customers, wholesalers, group purchasing organizations and other indirect customers. The Company’s payment terms were generally between thirty to ninety days.

Historically, the Company’s intangible asset was classified as an asset resulting from R&D activities. The Company determined the useful life of its asset resulting from R&D activities to be approximately 10 years, which was based on the remaining patent life, and was amortized on a straight-line basis. The Company performed an impairment test as of December 31, 2022 after identifying indicators of impairment, such as a decline in share price, the termination of the dedicated commercial team, sustained impacts of COVID-19 on the market and the discontinuation of commercialization of ANJESO, and based on the quantitative analysis an impairment loss of $19,681 was recorded during the year ended December 31, 2022, eliminating the remaining carrying value of the intangible asset.

On April 10, 2015, Societal CDMO, Inc. (“Societal CDMO”), formerly Recro Pharma, Inc., completed the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights to injectable meloxicam (the “Alkermes Transaction”). Pursuant to the purchase and sale agreement and subsequent amendment with Alkermes, as amended, governing the Alkermes Transaction, the Company agreed to pay to Alkermes up to an additional $140,000 in milestone payments including $60,000 upon regulatory approval payable over a seven-year period, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam.

Historically, the contingent consideration consisted of four separate components. The first component was (i) a $5,000 payment made in the first quarter of 2019 and (ii) a $5,000 payment made in the second quarter of 2019. The second components became payable upon regulatory approval in February 2020 and included (i) a $5,000 payment, which was paid in three installments during 2020 and 2021, and (ii) $45,000 payable in seven equal annual payments of approximately $6,400 beginning on the first anniversary of such approval, of which the first payment was made in the first quarter of 2021. The Company paid $1,200 of the second payment in 2022. The third component consisted of three potential payments, based on the achievement of specified annual revenue targets. The fourth component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future injectable meloxicam net sales, which was paid quarterly. In connection with the Transfer Agreement, the Company was relieved of its milestone payments previously owed to Alkermes in connection with the transaction and in the first quarter of 2023 reversed its contingent consideration balance, which was $19,900.

(amounts in thousands, except share and per share data)

Additionally as part of the Transfer Agreement, the Company wrote off its inventory balance as of March 31, 2023, which was fully reserved for as of December 31, 2022, and the remaining property and equipment balance related to equipment at the Alkermes facility that was transferred as part of the Transfer Agreement of $485.

(5) Business Acquisition

On June 29, 2023 ("Effective Date"), the Company acquired TeraImmune, Inc., in accordance with the terms of the Agreement and Plan of Merger (the "Merger Agreement"). Under the terms of the Merger Agreement, at the closing of the Acquisition the Company issued to the common stockholders of TeraImmune (the "Target Stockholders") an aggregate of 1,212,185 shares of common stock of Baudax Bio and 27,089.719 shares of Series X Preferred Stock, each share of which is convertible into 1,000 shares of common stock (subject to certain conditions as described below), of which 314,282 of common stock and 7,024 of preferred stock are classified as escrow shares at Closing. Under the terms of the Merger Agreement, all options to purchase or acquire shares of TeraImmune held by continuing employees (as defined in the Merger Agreement) were assumed by the Company and converted into options to purchase shares of common stock and Series X Preferred Stock on the same terms and conditions as applied to such options and restricted stock awards immediately prior to the Acquisition. Following the closing of the Acquisition, the Company had 6,961,867 shares of common stock issued and outstanding.

Pursuant to the Merger Agreement, the Company has agreed to hold a special meeting of shareholders (the "Special Meeting") to submit (i) the approval of the conversion of the Series X Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a), (ii) the approval to effect a reverse stock split of all of the Company's issued and outstanding shares of common stock, among other matters, to its shareholders for their consideration. In connection with these matters, the Company filed a preliminary proxy statement and other relevant materials with the Securities and Exchange Commission (the "SEC").

The Company incurred transaction costs of $575 for the three and six months ended June 30, 2023, which are included in the Company's condensed consolidated statement of operations.

The transaction was accounted for under the acquisition method of accounting with Baudax Bio as the acquirer under the guidance of ASC 810-10, "*Consolidation*". Under the acquisition method, the total purchase price of the acquisition is allocated to the net identifiable tangible and intangible assets acquired and liabilities assumed based on the fair values as of the date of such acquisition. The preliminary fair value of the consideration totaled approximately $9,702, summarized as follows:

		Amount
Common stock issued to TeraImmune's stockholders	$	476
Series X Convertible Preferred Stock issued to TeraImmune stockholders		9,040
Contingent consideration		118
Stock options and restricted stock allocated to total consideration paid		68
Total consideration paid	$	9,702

The Series X Preferred Shares are measured at fair value by taking the common stock equivalents at the Company's closing stock price on the Effective Date and discounting the value by 15% for a lack of marketability.

The Company recorded the assets acquired and liabilities assumed as of the date of the Acquisition based on the information available at that date. The following table presents the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the Acquisition date:

(amounts in thousands, except share and per share data)

Assets acquired:		
Cash and cash equivalents	$	142
Prepaid expenses and other current assets		52
Property and equipment, net		3,781
Goodwill		7,109
In-process research and development assets		3,500
Operating lease right-of-use assets		2,135
Total assets	$	16,719
Liabilities assumed:		
Accounts payable	$	515
Accrued expenses and other current liabilities		789
Convertible bond payable		1,000
Deferred tax liability		202
Operating lease liabilities		2,135
Derivative instrument		2,376
Total liabilities assumed	$	7,017
Net assets acquired	$	9,702

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been completed as of the date of this filing. Any changes in the estimated fair values of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the transaction will change the allocation of the purchase price. As such, the purchase price allocations for the acquisition are preliminary estimates, which are subject to change within the measurement period.

The fair value of IPR&D was capitalized as of the Acquisition date and accounted for as indefinite-lived intangible assets until completion or disposition of the assets or abandonment of the associated research and development efforts. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined based on the anticipated period of regulatory exclusivity and will be amortized within operating expenses. Until that time, the IPR&D assets will be subject to impairment testing and will not be amortized. The goodwill recorded related to the Acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of such acquisition. The goodwill recorded is not deductible for tax purposes.

The Convertible bond payable with an outstanding balance and accrued interest of $1,239 (see note 11) and the shares held by an investor in TIT were not converted into Baudax Bio shares upon the closing of the Merger (collectively “Unconverted Securities”). The Unconverted Shares are convertible into the Escrow Shares of 314,282 common shares and 7,024 preferred shares and are not included in issued and outstanding shares. Based on the Merger Agreement, if the Escrow Shares remain undistributed twelve months from the Closing Date (“Escrow End Date”), these Escrow Shares will be distributed on a pro rata basis to the holders of TeraImmune common stock as of immediately prior to the Merger. The Company accounts for the Escrows Shares and the potential distribution to the TeraImmune common stockholders as contingent consideration. The contingent consideration is liability classified at the time of acquisition and again as of June 30, 2023, as the underlying securities to be issued are substantially comprised of the Company’s Series X Preferred Stock. Contingent consideration is recorded at its estimated fair value at each reporting period using a probability weighted method using management’s estimates, level 3 observable inputs, and the likelihood of 3% and 5% for the TIT investor and bondholder, respectively, that the Escrow Shares will not be issued to the holders of the Unconverted Securities on or prior to the Escrow End Date. Changes in fair value of contingent consideration are recorded within the accompanying consolidated statements of operations.

The derivative instrument represents the obligation of the Company to issue shares of its Series X Preferred Stock and common stock, at the option of the investor in TIT. The derivative liability is recorded at its estimated fair value at each reporting period using a probability weighted method using management’s estimates and are level 3 observable inputs. Changes in fair value of derivative liability are recorded within the accompanying consolidated statements of operations.

Pro Forma Financial Information

The following unaudited pro forma financial information reflects the consolidated results of operations of the Company as if the Acquisition had taken place on January 1, 2023. The pro forma financial information is not necessarily indicative of the results of operations as they would have been had the transactions been effected on the assumed date:

(amounts in thousands, except share and per share data)

	Six Months Ended June 30, 2023
Operating expenses	$ 10,131
Loss from operations	(10,131)
Net loss from continuing operations	(12,953)
Net income	5,763

Nonrecurring pro forma transaction costs directly attributable to the Acquisition were $575 for the three and six months ended June 30, 2023 and have been deducted from the net loss presented above.

(6) Fair Value of Financial Instruments

The Company follows a three-level fair value hierarchy for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, warrants, and contingent consideration. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

•Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;

•Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and

•Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company has classified assets and liabilities measured at fair value on a recurring basis as follows:

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At June 30, 2023:			
Assets:			
Cash equivalents (See Note 7)			
Money market mutual funds	$ 791	$ —	$ —
Total cash equivalents	$ 791	$ —	$ —
Liabilities:			
Derivative liability	$ —	$ —	$ 5,246
Contingent consideration (See Note 5)	—	—	260
	$ —	$ —	$ 5,506
At December 31, 2022:			
Assets:			
Cash equivalents (See Note 7)			
Money market mutual funds	$ 2,241	$ —	$ —
Total cash equivalents	$ 2,241	$ —	$ —

(amounts in thousands, except share and per share data)

As of June 30, 2023, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts payable and accrued expenses, which approximate fair value due to the short-term nature of these instruments. The fair value of debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of debt approximated fair value at June 30, 2023 due to the fact that the debt arrangements reflect market terms from recent transactions.

The reconciliation of liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Contingent Consideration and Derivative Liability
Balance at December 31, 2022	$ —
Acquisition of contingent consideration and derivative liability	2,494
Remeasurement	3,012
Total at June 30, 2023	$ 5,506
Current portion as of June 30, 2023	$ 5,506
Long-term portion as of June 30, 2023	—

See Note 5 for discussion on contingent consideration.

(7) Cash Equivalents

The following is a summary of cash equivalents:

	June 30, 2023			
Description	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Money market mutual funds	$ 791	$ —	$ —	$ 791
Total cash equivalents	$ 791	$ —	$ —	$ 791

	December 31, 2022			
Description	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Money market mutual funds	$ 2,241	$ —	$ —	$ 2,241
Total cash equivalents	$ 2,241	$ —	$ —	$ 2,241

As of June 30, 2023 and December 31, 2022, the Company's cash equivalents had maturities of one month.

(8) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	June 30, 2023	December 31, 2022
Building and improvements	$ 3,345	$ 166
Furniture, office and computer equipment	292	306
Manufacturing and laboratory equipment	532	—
	4,169	472
Less: accumulated depreciation and amortization	388	463
Property and equipment, net	$ 3,781	$ 9

Depreciation and amortization expense for the three and six months ended June 30, 2023 was $1 and $4, respectively. Depreciation expense for the three and six months ended June 30, 2022 was $15 and 29, respectively.

(amounts in thousands, except share and per share data)

(9) Leases

The Company is a party to various operating leases in (i) Malvern, Pennsylvania, (ii) Dublin, Ireland and (iii) Germantown, Maryland for office and lab space and office equipment.

The Company determines if an arrangement is a lease at inception or upon acquisition of previous arrangements through a merger. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Lease terms vary based on the nature of operations. All leased facilities recorded on the unaudited consolidated balance sheet are classified as operating leases with remaining lease terms between 5 and 8 years. Most leases contain specific renewal options where notice to renew must be provided in advance of lease expiration or automatic renewals where no advance notice is required. Periods covered by an option to extend the lease were included in the non-cancellable lease term when exercise of the option was determined to be reasonably certain. Costs determined to be variable and not based on an index or rate were not included in the measurement of operating lease liabilities. As most leases do not provide an implicit rate, the Company's effective interest rate was used to discount its lease liabilities.

The Company's leases with an initial term of twelve months or less that do not have a purchase option or extension that is reasonably certain to be exercised are not included in the right of use asset or lease liability on the Consolidated Balance Sheets. Lease expense is recognized on a straight-line basis over the lease term.

As of June 30, 2023, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments
Remainder of 2023	$ 336
2024	690
2025	702
2026	724
2027	745
2028 and thereafter	1,897
Total lease payments	5,094
Less imputed interest	(2,184)
Total operating lease liability	$ 2,910

As of June 30, 2023, the weighted average remaining lease term was 7 years and the weighted average discount rate was 17%.

As of June 30, 2022, the weighted average remaining lease term was 6 years and the weighted average discount rate was 23%.

The components of the Company's lease cost were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost	$ 70	$ 71	$ 140	$ 145
Short-term lease cost	1	35	36	73
Total lease cost	$ 71	$ 106	$ 176	$ 218

Cash paid for amounts included in the measurement of lease liabilities, which is included in operating cash flows, was $192 and $187 for the six months ended June 30, 2023 and 2022, respectively.

(amounts in thousands, except share and per share data)

(10) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2023	December 31, 2022
Payroll and related costs	$ 623	$ 656
Professional and consulting fees	966	789
Other research and development costs	536	593
Interest payable	362	94
Other	161	1
	$ 2,648	$ 2,133

(11) Debt

Credit Agreement

The following table summarizes the components of the carrying value of the Company's credit agreement:

	June 30, 2023	December 31, 2022
Credit Agreement	$ 10,000	$ 10,000
Payment of principal	(5,744)	(2,244)
Unamortized deferred issuance costs	—	(828)
Accrued amendment fee	378	—
Exit fee accretion	227	191
Total debt	$ 4,861	$ 7,119
Current portion	$ 4,861	$ 5,600
Long-term portion, net	—	1,519

On May 29, 2020 (the “Credit Agreement Closing Date”), the Company entered into a $50,000 Credit Agreement (the “Credit Agreement”) by and among the Company, Wilmington Trust, National Association, in its capacity as the agent (“Agent”), and MAM Eagle Lender, LLC, as the lender (together with any other lenders under the Credit Agreement from time to time, collectively, the “Lenders”). The Credit Agreement provides for a term loan in the original principal amount of $10,000 (the “Tranche One Loans”) funded on the Credit Agreement Closing Date. Pursuant to the terms of the Credit Agreement, there are four additional tranches of term loans, in an aggregate original principal amount of $40,000 (the “Tranche Two Loans”, “Tranche Three Loans”, “Tranche Four Loans” and the “Tranche Five Loans”, and collectively with the Tranche One Loans, the “Term Loans” and each a “Term Loan”). As of June 30, 2023, no funds have been drawn from the additional tranches and are not expected to be drawn in the future.

The Term Loans will bear interest at a per annum rate equal to 13.5%, with monthly, interest-only payments until the date that is three years prior to the Maturity Date (as defined below) (the “Amortization Date”). The maturity date of the Credit Agreement is May 29, 2025, but may be extended to May 29, 2026 provided that the EBITDA (as defined in the Credit Agreement) for the consecutive twelve-month period ending on or immediately prior to May 29, 2022 is greater than $10,000 (such date, “Maturity Date”), which the Company did not achieve. Beginning on the Amortization Date, the Company was obligated to pay amortization payments (in addition to the interest stated above) on such date and each month thereafter in equal month installments of principal based on an amortization schedule of thirty-six months. Any unpaid principal amount of the Term Loans is due and payable on the Maturity Date.

Subject to certain exceptions, the Company is required to make mandatory prepayments of the Term Loans, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events. The Company may make voluntary prepayments in whole or in part, subject to a prepayment premium equal to (i) with respect to any prepayment paid on or prior to the third anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the third anniversary of the date each such loan is funded), the remaining scheduled payments of interest that would have accrued on the Term Loans being prepaid, repaid or accelerated, but that remained unpaid, in no event to be less than 5.0% of the principal amount of the Term Loan being prepaid, and (ii) with respect to any prepayment paid after the third but prior to the fourth anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the fourth anniversary of the date each such loan is funded), 3.0% of the principal amount of the Term Loan being prepaid. In addition, an exit fee will be due and payable upon prepayment or repayment of the Term Loans (including, without limitation, on the Maturity Date) equal to the lesser of 2.5% of the sum of the aggregate principal amount of the Term Loans advanced or approved to be advanced by the Lenders and $700; provided that such exit fee will be equal to $700 if fee is paid in conjunction with a change of control that occurs in connection with the payoff or within 6 months thereof. As of June 30, 2023, the Company will have to pay a 2.5% exit fee, which is $250 at the current outstanding loan balance and is being accreted to the carrying amount of the debt using the effective interest method over the term of the loan.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants including a minimum liquidity requirement of $5,000 at all times (the "Minimum Liquidity Covenant") and minimum EBITDA levels that the Company may need to satisfy on a quarterly basis beginning in September 2021, subject to borrowing levels. As of June 30, 2023, the Company was in compliance with the Minimum Liquidity Covenant as the minimum EBITDA criteria is not applicable until additional tranches are drawn. As of June 30, 2023, borrowings under the Credit Agreement are classified based on their schedule maturities.

In connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 376 shares of the Company's common stock, at an exercise price equal to $6,426.00 per share. See Note 13(c) for additional information. The warrant is exercisable through May 29, 2027.

The Company recorded debt issuance costs for the Credit Agreement of $1,496 plus the fair value of warrants of $1,423, which were being amortized using the effective interest method over the term of Credit Agreement prior to Amendment No. 5 as noted below. Debt issuance cost amortization is included in interest expense within the Consolidated Statements of Operations. The Company recorded debt issuance cost amortization related to the Credit Agreement prior to Amendment No. 5 of $263 for both the three and six months ended June 30, 2023. The Company recorded debt issuance cost amortization related to the Credit Agreement of $209 and $421 for the three and six months ended June 30, 2022, respectively.

On August 1, 2022, the Company entered into Amendment No. 1 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the lenders waived any default under the credit agreement (including the imposition of a default interest rate with respect to the default) resulting from our failure to comply with the Minimum Liquidity Covenant. In addition, the Amendment, among other items, (i) provides that 30% of any cash proceeds received by the Company from certain potential strategic licensing transactions shall be used to prepay amounts outstanding under the credit agreement; and (ii) decreases the amount of cash the Company is required to maintain pursuant to the Minimum Liquidity Covenant to $3,000 for a period beginning on August 1, 2022, and ending on August 31, 2022, at which point the amount required pursuant to the Minimum Liquidity Covenant shall increase to $5,000.

On October 24, 2022, the Company entered into Amendment No. 2 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the Credit Agreement is amended such that the Company must repay the principal thereunder (i) on the first business day of each month until the Interest Payment Date on December 1, 2022, in equal monthly installments of principal based on an amortization schedule of 36 months, (ii) an additional payment of principal in the amount of $300 prior to December 31, 2022 and (iii) commencing on the Interest Payment Date on January 2, 2023 and on each Interest Payment Date thereafter until the obligations have been repaid in full, the principal amount of $500. In addition, the Amendment decreases the minimum cash covenant the Company is required to maintain under the Credit Agreement to (i) $3,000 for the period beginning on October 1, 2022, and ending on November 30, 2022, (ii) $4,500 for the period beginning on December 1, 2022, and ending on February 28, 2023, and (iii) $4,000 from and after March 1, 2023. Further, the Company has agreed that prior to December 31, 2022, it shall not, without the prior written consent of the Lenders, make or permit any payment under its agreements with Alkermes. In consideration for the Amendment, the Company agreed to pay the Agent an amendment fee of $5 and the Lender an amendment fee of $200.

On December 1, 2022, the Company entered into Amendment No. 3 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the amendment decreases the minimum cash covenant the Company is required to maintain under the credit agreement to (a) from October 1, 2022 to December 6, 2022 to not be less than $3,000 at any time, (b) from December 7, 2022 to February 28, 2023 to not be less than $4,500, and (c) from and after March 1, 2023 to not be less than $4,000.

In January 2023, the Company entered into Amendment No. 4 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the credit agreement was amended such that the Company must make (i) a payment of principal in the amount of $500 on January 3, 2023, (ii) a payment of principal in the amount of $300 on February 1, 2023 and March 1, 2023, and (iii) on the interest payment date on April 3, 2023 and on each interest payment date thereafter until the obligations are repaid in full, a payment in the principal amount of $500. In addition, the amendment decreases the minimum cash covenant the Company is required to maintain under the credit agreement, or the Minimum Liquidity Covenant, to (i) $3,000 for the period beginning on October 1, 2022, and ending on December 6, 2022, (ii) $4,500 for the period beginning on December 7, 2022, and ending on January 10, 2023, (iii) $2,225 for the period beginning on January 11, 2023, and ending on February 28, 2023, and (iv) $3,000 from and after March 1, 2023. Further, the Company agreed that prior to April 30, 2023, it will not, without the prior written consent of MAM Eagle Lender, make or permit any payment under its agreements with Alkermes.

On March 29, 2023, the Company entered into Amendment No. 5 and Consent to Credit Agreement whereby MAM Eagle Lender consented to the transactions contemplated by the Transfer Agreement (as defined above) and agreed to release and discharge any liens granted or held by the lenders in respect of the assets discussed in the Transfer Agreement. The parties also agreed to, among other things, amend the minimum liquidity covenants under the Credit Agreement to require that the Company maintains $2,500 of liquidity at all times. In connection with Amendment No. 5, the Company issued warrants to MAM Eagle Lender to purchase an aggregate of 785,026 shares of the Company's common stock, par value $0.01 per share at an exercise price equal to $1.8951 per share.

In connection with the Acquisition, the Company entered into a Forbearance Agreement, dated as of June 29, 2023, by and among the Company, the Lenders and the Agent, solely in its capacity as administrative and collateral agent for the Lenders, pursuant to which the Lenders agreed to forbear their rights to exercise any rights and remedies with respect to any default under the Credit Agreement, resulting from the Acquisition, for a period of up to 30 days following the closing of the Acquisition. On July 30, 2023, the parties amended the Forbearance Agreement to extend such deadline until October 31, 2023.

As a result of Amendment No. 5, the Company performed a cash flow analysis to determine if the terms of the amended agreement were substantially different from those of the previous debt agreement. Due to the amendment fee and the fair value of the warrants issued, the Company concluded the terms are substantially changed in accordance with ASC 470-50, *Debt – Modifications and Extinguishments*. ASC 470-50 requires accounting for the amendment as a debt extinguishment and not a debt modification. The Company recorded a loss on debt extinguishment of $2,196 in the first quarter of 2023, which represents the difference between the net carrying value of the existing debt and the reacquisition cost of the amended terms of the agreement and is attributable to unamortized debt issuance costs, the fair value of the Amendment No. 5 warrants and the Amendment No.5 fee.

Based on the terms of the amended agreement, as of June 30, 2023, the effective interest rate was 14.85%, which takes into consideration the accretion of the exit fee.

As a result of the liquidity conditions discussed in Note 2, the Company is not expected to be able to comply with the Minimum Liquidity Covenant, as amended, over the next twelve months without additional capital financing. If the Company is unable to maintain its Minimum Liquidity Covenant, it is reasonably possible that the Lenders could demand repayment of the borrowings under the Credit Agreement during the next twelve months.

Bond Payable

On March 22, 2022, TeraImmune entered into the 5% Convertible Term Loan pursuant to which it borrowed an aggregate of $1,000 and accrued interest at a rate of 5% per annum during the period from April 8, 2022 to the maturity date of November 30, 2022, at which date the principal and accrued interest was to be paid in a lump sum. TeraImmune failed to repay the loan on the maturity date and, as a result, the note became subject to a default interest penalty of 20% on the defaulted balance as of November 30, 2022. The bond is convertible into 83,128 shares of common stock and 1,858 Series X Preferred Shares of the Company. Accrued interest of $239 as of June 30, 2023 is included in the Accrued expenses and other current liabilities line on the balance sheet. See additional discussion in Note 5.

Employee Promissory Notes

In October 2022, TeraImmune entered into promissory note agreements for accrued salaries with its employees (the "Employee Promissory notes"). The Employee Promissory notes deferred the payment of salaries of all TeraImmune employees and management by between 20-50% until such time as defined in the note agreements. The Employee Promissory notes provide that if TeraImmune is unable to repay these notes by December 31, 2022, 5% simple interest would be paid along with the accrued amounts of deferred compensation. As of June 30, 2023, the Employee Promissory notes totaled $241 and is included in the Accrued expenses and other current liabilities line on the balance sheet.

(12) Commitments and Contingencies

(a) Licenses and Supply Agreements

NMB License

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents ("NMBs") and a proprietary reversal agent from Cornell University ("Cornell"). The NMBs and reversal agent are referred to herein as the NMB Related Compounds. The NMB Related Compounds include one novel intermediate-acting NMB that has initiated Phase I clinical trials and two other agents, a novel short-acting NMB, and a rapid-acting reversal agent specific to these NMBs. The Company is obligated to make: (i) an annual license maintenance fee payment to Cornell in the remaining range of $70 to $125 until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments to Cornell upon the achievement of certain milestones, up to a maximum, for each NMB Related Compound, of $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 for European regulatory approval and commercialization milestones. The Company is obligated to pay Cornell royalties on net sales of the NMB Related Compound at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company reimburses Cornell for its ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds. Through June 30, 2023, no such milestones have been achieved.

HA FVIII TCR Agreement

On August 5, 2019, TeraImmune entered into an exclusive worldwide license agreement (the "HA FVIII TCR Agreement") with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") for certain technologies used to create FVIII specific TCR or BAR expressing Tregs for human uses. Pursuant to the FVIII TCR Agreement, TeraImmune has paid a license royalty fee and annual royalties of $50 to HJF since September 2019.

BML Agreement

On August 26, 2019, TeraImmune entered into the non-exclusive Biological Materials License Agreement ("BML Agreement") with the National Cancer Institute ("NCI"), a part of National Institute for Health ("NIH"), which is part of the U.S. Government Department of Health and Human Services. This agreement allows TeraImmune to use the pMSGV1 vector for the production of T cell products transduced with the retroviral vectors. Pursuant to the BMLA Agreement, TeraImmune has paid a license execution fee and annual royalties of $11 to NIH since August 2019.

HA ODN Agreement

On June 18, 2020, TeraImmune entered into an exclusive license agreement (the "HA ODN Agreement") with National Institute of Allergy and Infectious Diseases ("NIAID"), a part of NIH. This license agreement allows TeraImmune to use the rights of patent for producing T cell populations enriched for stable regulatory Tregs aimed at developing Treg cell therapy for patients with hemophilia A who have inhibitory anti-FVIII auto-antibodies. Pursuant to the HA ODN Agreement, TeraImmune has paid a license royalty fee and annual royalties of $60 to NIAID since August 2020. The HA ODN Agreement also requires the payment of milestones and royalties upon the achievement of certain regulatory and commercialization milestones.

iTreg Agreement

On November 11, 2020, TeraImmune entered into an exclusive worldwide license agreement (the "iTreg Agreement") with HJF for technology used for producing methods of induced regulatory T cells ("iTreg") and the use of such technology in humans. The license was pending the status of provisional filing on the signing date, and TeraImmune agreed to take responsibility for the maintenance and prosecution of the Patent Rights in consultation with HJF on all strategic global filing and prosecution decisions. Under the iTreg Agreement, TeraImmune paid a license fee of $25 to HJF in December 2020.

(b) Purchase Commitments

As of June 30, 2023, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of $64 primarily related to goods and services from development activities.

(c) Certain Compensation and Employment Agreements

The Company is party to employment agreements with its named executive officers. As of June 30, 2023, these employment agreements provide for, among other things, annual base salary in an aggregate amount of not less than $1,067, from that date through September 2024.

(13) Capital Structure

(a) Common Stock

On November 21, 2019, the Company separated from Societal CDMO as a result of a special dividend distribution of all the outstanding shares of its common stock to Societal CDMO shareholders. On the distribution date, each Societal CDMO shareholder received one share of Baudax Bio's common stock for every two and one-half shares of Societal CDMO common stock held of record at the close of business on November 15, 2019. Upon the distribution, 6,712 shares of common stock were issued.

The Company is authorized to issue 190,000,000 shares of common stock, with a par value of $0.01 per share.

On March 1, 2022, the Company closed an underwritten public offering of 45,791 shares of its common stock, pre-funded warrants to purchase 41,929 shares of common stock at an exercise price of $0.40 per share and warrants to purchase 87,719 shares of common stock at an exercise price of $130.00 per share, as well as up to 13,158 additional shares of common stock and/or additional warrants to purchase up to 13,158 shares of common stock, which may be purchased pursuant to a 30-day option to purchase additional securities granted to H.C. Wainwright & Co., LLC (the "Underwriter") by the Company. The public offering price for each share of common stock and accompanying warrant to purchase one share of common stock was $114.00, and the public offering price for each pre-funded warrant and accompanying warrant was $113.60. As compensation to the Underwriter, the Company agreed to pay to the Underwriter a cash fee of 7.0% of the gross proceeds, plus a cash management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Underwriter warrants to purchase 5,263 shares of common stock at an exercise price of $142.50 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 2,847 warrants. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $8,791.

On May 17, 2022, the Company entered into a securities purchase agreement with institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "May 2022 Offering"), 41,152 shares of the Company's common stock, par value $0.01 per share, and, in a concurrent private placement, warrants exercisable for up to an aggregate of 41,152 shares of Common Stock at a combined offering price of $48.60 per share and associated warrant. The warrants have an exercise price of $43.60 per share. Each warrant is exercisable for one share of common stock and was exercisable immediately upon issuance. The warrants will have a term of five years from the issuance date. As compensation to H.C. Wainwright & Co., LLC as placement agent in connection with the offering, the Company agreed to pay to the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering and certain expenses. The Company also issued to designees of the placement agent warrants to purchase up to 6.0% of the aggregate number of shares of common stock sold in the transactions, or warrants to purchase up to 2,469 shares of common stock. The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the offering price per share (or $60.75 per share). The placement agent warrants will expire on May 17, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $1,720.

On September 1, 2022, the Company closed a best efforts public offering of: (i) 188,872 shares of its common stock, par value $0.01 per share and accompanying Series A-1 warrants ("Series A-1 warrants") to purchase 188,872 shares of Common stock and Series A-2 warrants ("Series A-2 warrants", and together with the Series A-1 warrants, "Series A warrants") to purchase 188,872 shares of Common Stock, at a combined public offering price of $21.00 per share and Series A warrants and (ii) Series B pre-funded warrants ("Series B pre-funded warrants") to purchase 106,607 shares of Common Stock and accompanying Series A-1 warrants to purchase 106,607 shares of Common Stock and Series A-2 warrants to purchase 106,607 shares of Common stock at a combined public offering price of $20.60 per Series B pre-funded warrant and Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series B pre-funded warrant. The Series A warrants have an exercise price of $21.00 per share of Common Stock. The Series A-1 warrants are exercisable upon issuance and will expire five years from the date of issuance. The Series A-2 warrants are exercisable upon issuance and will expire thirteen months from the date of issuance. The exercise price of the Series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A warrants. Subject to certain ownership limitations, the Series B pre-funded warrants are immediately exercisable and were exercised at a nominal consideration of $0.40 per share of Common Stock upon the closing of the transaction. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the Offering, the Company paid a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 17,728 shares of common stock. The placement agent warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $26.25 per share and expire on August 29, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $5,044.

On December 6, 2022 the Company closed a best efforts public offering of: (i) 54,787 shares of its common stock, par value $0.01 per share and accompanying Series A-3 warrants to purchase 54,787 shares of common stock and Series A-4 warrants to purchase 54,787 shares of common stock, at a combined public offering price of $4.795 per share and accompanying series A warrants and (ii) series C pre-funded warrants to purchase 988,000 shares of common stock and accompanying series A-3 warrants to purchase 988,000 shares of common stock and series A-4 warrants to purchase 988,000 shares of common stock at a combined public offering price of $4.785 per series C pre-funded warrant and accompanying series A warrants, which was equal to the public offering price per share of common stock and accompanying series A warrants less the $0.01 per share exercise price of each such series C pre-funded warrant. The series A warrants have an exercise price of $4.50 per share of common stock. The series A-3 warrants are exercisable upon issuance and will expire on December 6, 2027. The series A-4 warrants are exercisable upon issuance and will expire on January 8, 2024. The exercise price of the series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A Warrants. The Series C prefunded warrants have been exercised in full as of December 31, 2022. As compensation to H.C. Wainwright & Co., LLC as the exclusive placement agent in connection with the offering, the Company paid the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 62,567 shares of common stock. The Placement Agent Warrants have substantially the same terms as the series A warrants, except that the placement agent warrants have an exercise price equal to $5.99375 per share and expire on December 2, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $3,916.

On May 1, 2023 the Company closed a best efforts public offering of: (i) 1,326,175 shares of its common stock, par value $0.01 per share and accompanying Series A-5 warrants to purchase 1,326,175 shares of Common stock and Series A-6 warrants to purchase 1,326,175 shares of common stock, at a combined public offering price of $1.15 per share and accompanying Series A warrants and (ii) Series D pre-funded warrants to purchase 2,152,087 shares of common stock and accompanying Series A-5 warrants to purchase 2,152,087 shares of common stock and Series A-6 warrants to purchase 2,152,087 shares of common stock at a combined public offering price of $1.14 per Series D pre-funded warrant and accompanying Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series D pre-funded warrant. The Series A warrants have an exercise price of $1.15 per share of common stock. The Series A-5 warrants are exercisable upon issuance and will expire on May 1, 2028. The Series A-6 warrants are exercisable upon issuance and will expire on November 1, 2024. Subject to certain ownership limitations described in the Series D pre-funded warrants, the Series D pre-funded warrants were immediately exercisable and were fully exercised at a nominal consideration of $0.01 per share of common stock upon closing. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the offering, the Company paid the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering,

plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 208,696 shares of common stock. These warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $1.4375 per share and expire on April 26, 2028. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $3,257.

(b) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of June 30, 2023, there were 20,066 shares of Preferred Stock issued and outstanding.

On September 19, 2022, the board of directors of the Company declared a dividend of one one-thousandth (1/1,000th) of a share of Series B Preferred Stock, par value $0.01 per share ("Series B Preferred Stock"), for each outstanding share of the Company's common stock, par value $0.01 per share to shareholders of record on September 29, 2022 (the "Record Date"). The shares of Series B Preferred Stock were distributed to such recipients on October 3, 2022. Each share of Series B Preferred Stock entitles the holder thereof to 1,000,000 votes per share. The outstanding shares of Series B Preferred Stock vote together with the outstanding shares of Common Stock of the Company as a single class exclusively with respect to (1) any proposal to adopt an amendment to the Company's Amended and Restated Articles of Incorporation, as amended, to reclassify the outstanding shares of common stock into a smaller number of shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split") and (2) any proposal to adjourn any meeting of shareholders called for the purpose of voting on the Reverse Stock Split. The Series B Preferred Stock will not be entitled to vote on any other matter, except to the extent required under the Pennsylvania Business Corporation Law.

In September 2022, 20,003.745 shares of Series B Preferred Stock were declared as a stock dividend and issued on October 3, 2022. On November 3, 2022, all of our outstanding shares of Series B Preferred Stock were redeemed for nominal consideration pursuant to the terms of the Series B Preferred Stock.

Non-voting Convertible Preferred Stock

In connection with the acquisition of TeraImmune, the Company issued 27,089.719 shares of Series X Preferred Stock (including 7,024 escrow shares). Holders of Series X Preferred Shares are not entitled to vote except for specific corporate matters including (i) changes to the rights and preferences of the Series X Preferred Stock, (ii) issuance of additional Series X Preferred Stock, and (iii) enter into a fundamental transaction such as a sale of the Company. Other key provisions of the Series X Preferred Stock are as follows:

- Conversion - upon obtaining shareholder approval, each share of Series X Preferred Stock will automatically convert into 1,000 shares of common stock, subject to beneficial ownership limitations.
- Dividends - Series X Preferred Stock participates in any dividends with common shareholders on an as-converted basis.
- Liquidation - The Series X Preferred Stock ranks on parity with our common stock upon any liquidation, dissolution or winding up of the Company.
- Redemption - In the event the Company is unable to obtain an affirmative shareholder vote to permit conversion, each holder of Series X Preferred Stock may elect, at the holder's option, to have the shares of Series X Preferred Stock be redeemed by the Company and equal to the estimated fair value of the Series X Preferred Stock share at the time of redemption. Due to this redemption feature, the Series X Preferred Stock has been classified within temporary equity on the consolidated balance sheet at June 30, 2023.

(c) Warrants

On May 29, 2020, in connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 376 shares of common stock, at an exercise price equal to $6,426.00 per share (see Note 11).

On October 19, 2020, the Company entered into Warrant Exchange Agreements (each, an "Exchange Agreement") with certain holders (each, a "Holder") of the Company's outstanding March Series A Warrants and March Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their March Series A Warrants or March Series B Warrants, in each case for 0.2 shares of the Company's common stock per warrant (rounded up to the nearest whole share) (the "Exchange"). The Company issued 848 shares of its common stock to the participating Holders as a result of the Exchange.

As a result of the Exchange, pursuant to certain price adjustment provisions in the warrants, the exercise price of each of the March Series A Warrants or March Series B Warrants (including warrants held by holders not participating in the Exchange) that were not exchanged were adjusted to $1.8951, for each share of common stock underlying such warrant. Pursuant to the Exchange Agreements, any outstanding warrant held by a Holder participating in the Exchange (i) was amended to remove certain anti-dilution and variable pricing protections and (ii) in the case of March Series A Warrants not exchanged by a participating Holder, was amended to adjust the expiration date of such March Series A Warrants to April 26, 2021 (which is the expiration date of the March Series B Warrants). The March Series A and Series B warrants were liability classified prior to the Exchange because they contained anti-dilution provisions that did not meet the standard definition of anti-dilution provisions. The Company recorded a mark-to-market adjustment to record the March Series A and Series B warrant at their fair values immediately prior to the Exchange and then reclassified the remaining balance of $21,858 to equity as a result of the issuance of shares and the removal of the anti-dilution and variable pricing protections in the Exchange.

On January 21, 2021, the Company entered into an agreement with an institutional investor, pursuant to which the Company agreed to issue and sell, in an offering (the "January Offering"), warrants exercisable for an aggregate of 7,358 shares of common stock of the Company (the "January Warrants") at an offering price of $175.00 per warrant in exchange for the exercise of the institutional investor's existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of $1,652.00 per warrant. The January Warrants have an exercise price of $2,240.00 per share.

As compensation to the Placement Agent, in connection with the January Offering, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants), plus a management fee equal to 1.0% of the gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants) and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase 441 shares of common stock (the "January Placement Agent Warrants") at an exercise price of $2,800.00 per share.

On August 24, 2022, the Company entered into warrant amendment agreements (the "Warrant Amendment Agreements") with certain holders of the Company's (i) Series A Warrants to purchase 7,234 shares of common stock with an exercise price of $1,680.00 per share, (ii) Warrants to purchase 7,358 shares of common stock with an exercise price of $2,240.00 per share, (iii) Warrants to purchase 10,021 shares of common stock with an exercise price of $1,260.00 per share, (iv) Warrants to purchase 9,062 shares of common stock with an exercise price of $448.00 per share, and (v) Warrants to purchase 88,615 shares of common stock with an exercise price of $130.00 per share (the "Existing Warrants"). Under the Warrant Amendment Agreements, the Company agreed to amend the Existing Warrants by lowering the exercise price of the Existing Warrants to $23.92 per share. The warrant modification resulted in an increase in the fair value of warrants of $1,151. Subsequent to the warrant amendment, the Company issued 2,875 shares of common stock upon exercise of a portion of the amended warrants for net proceeds of $69.

On December 2, 2022, the Company entered into a warrant amendment agreement (the "December Warrant Amendment Agreement") with a certain holder of the Company's (i) warrants to purchase 7,234 shares of common stock with an exercise price of $23.92 per share, (ii) warrants to purchase 7,358 shares of common stock with an exercise price of $23.92 per share, (iii) warrants to purchase 6,013 shares of common stock with an exercise price of $23.92 per share, (iv) Warrants to purchase 5,143 shares of common stock with an exercise price of $23.92 per share, (v) warrants to purchase 48,246 shares of common stock with an exercise price of $23.92 per share, (vi) Series A-1 warrants to purchase 14,404 shares of common stock with an exercise price of $43.60 per share, (vii) Series A-2 warrants to purchase 142,858 shares of common stock with an exercise price of $21.00 per share and (viii) warrants to purchase 142,858 shares of common stock with an exercise price of $21.00 per share (collectively, the "December Existing Warrants"). Under the December Warrant Amendment Agreement, the Company (i) agreed to amend the December Existing Warrants by lowering the exercise price of the December Existing Warrants to $4.50 per share and (ii) amend the expiration date of the December Existing Warrants to December 6, 2027, in

(amounts in thousands, except share and per share data)

each case effective on December 6, 2022. The warrant modification resulted in an increase in the fair value of warrants of $746.

In January 2023, the Company issued 961,787 shares of common stock upon the exercise of warrants for proceeds of $4,328.

In March 2023, in connection with Amendment No. 5, the Company issued warrants to MAM Eagle Lender to purchase an aggregate of 785,026 shares of the Company's common stock, par value $0.01 per share at an exercise price equal to $1.8951 per share.

As of June 30, 2023, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

	Number of Shares		Exercise Price per Share	Expiration Date
March Series A Warrants (non-participating holders)	15	$	1.8951	March 26, 2025
MAM Eagle Lender Warrant	376	$	6,426.00	May 29, 2027
November Series A Warrants	7,234	$	4.50	December 6, 2027
November Placement Warrants	433	$	2,073.75	November 24, 2025
December Placement Warrants	441	$	2,038.75	December 18, 2025
January Warrants	7,358	$	4.50	December 6, 2027
January Placement Warrants	441	$	2,800.00	January 21, 2026
February Placement Warrants	471	$	2,800.00	February 8, 2026
May Warrants	4,008	$	23.924	June 1, 2027
May Warrants, repriced	6,013	$	4.50	December 6, 2027
May Placement Warrants	601	$	1,487.50	May 31, 2026
December 2021 Warrants	3,918	$	23.924	June 27, 2027
December 2021 Warrants, repriced	5,143	$	4.50	December 6, 2027
December 2021 Placement Agent Warrants	724	$	448.00	December 27, 2026
March 2022 Warrants	1,952	$	130.00	March 1, 2027
March 2022 Warrants, repriced	37,492	$	23.924	March 1, 2027
March 2022A Warrants, repriced	48,246	$	4.50	December 6, 2027
March 2022 Underwriter Warrants	5,263	$	142.50	February 24, 2027
May 2022 Warrants	26,748	$	43.60	May 19, 2027
May 2022 Warrants, repriced	14,404	$	4.50	December 6, 2027
May 2022 Placement Agent Warrants	2,469	$	60.752	May 17, 2027
August 2022 Series A-1 Warrants	152,612	$	21.00	September 1, 2027
August 2022 Series A-1 Warrants, repriced	142,858	$	4.50	December 6, 2027
August 2022 Series A-2 Warrants	152,612	$	21.00	October 2, 2023
August 2022 Series A-2 Warrants, repriced	142,858	$	4.50	December 6, 2027
August 2022 Placement Agent Warrants	17,728	$	26.25	August 29, 2027
December 2022 Series A-3 Warrants	1,042,787	$	4.50	December 6, 2027
December 2022 Placement Agent Warrants	62,567	$	5.99375	December 2, 2027
MAM Eagle Lender Amendment No. 5 Warrant	785,026	$	1.89510	March 29, 2033
April 2023 Series A-5 Warrants	3,478,262	$	1.15	May 1, 2028
April 2023 Series A-6 Warrants	3,478,262	$	1.15	November 1, 2024
April 2023 Placement Agent Warrants	208,696	$	1.43750	April 26, 2028

(amounts in thousands, except share and per share data)

With the exception of the March Series A Warrants to purchase 15 shares of common stock related to the public offering and held by non-participating investors in the Exchange that are liability classified as they contain antidilution provisions that do not meet the standard definition of antidilution provisions, the remaining warrants outstanding are equity classified. As of June 30, 2023 the liability warrants had a nominal fair value.

(14) Stock-Based Compensation

The Baudax Bio 2019 Equity Incentive Plan

The Company adopted the Baudax Bio 2019 Plan that allows for the grant of stock options, stock appreciation rights and stock awards for an initial total of 2,142 shares of common stock. On December 1st of each year, pursuant to the "Evergreen" provision of the Baudax Bio 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1st of that year or such lower amount as determined by the Board of Directors. The total number of shares authorized for issuance under the Baudax Bio 2019 Plan as of June 30, 2023 is 31,581 shares. As of June 30, 2023, 19,220 shares are available for future grants under the Baudax Bio 2019 Plan.

Stock Options:

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. There were no options granted during the six months ended June 30, 2023 or 2022.

The following table summarizes Baudax Bio stock option activity during the six months ended June 30, 2023:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2022	1,939	$ 3,525.88	6.5 years
Expired/forfeited/cancelled	(402)	$ 3,875.35	
Balance, June 30, 2023	1,537	$ 3,434.48	7.7 years
Vested	1,204	$ 3,513.14	7.6 years
Vested and expected to vest	1,537	$ 3,434.48	7.7 years

Included in the table above are 28 stock options outstanding as of June 30, 2023 that were granted outside of the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Restricted Stock Units (RSUs):

The following table summarizes Baudax Bio RSUs activity during the six months ended June 30, 2023:

	Number of shares	Weighted average grant date fair value
Balance, December 31, 2022	10,611	$ 116.81
Granted	—	—
Vested and settled	(7,558)	3.41
Expired/forfeited/cancelled	(386)	1,318.71
Balance, June 30, 2023	2,667	$ 150.34
Expected to vest	2,667	

Included in the table above are 2 shares of time-based RSUs outstanding as of June 30, 2023 that were granted outside of the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Stock-Based Compensation Expense:

Stock-based compensation expense from continuing operations for the six months ended June 30, 2023 and 2022 was $389 and $786, respectively.

(amounts in thousands, except share and per share data)

As of June 30, 2023, there was $444 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 0.7 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2023, there was no aggregate intrinsic value of the vested and unvested options.

The TeraImmune 2019 Equity Plan

In 2019, TeraImmune adopted the TeraImmune 2019 Stock Option and Restricted Stock Plan (the "TeraImmune 2019 Plan") that provides for the granting of incentive stock options, non-statutory stock options and restricted stock awards. As of June 30, 2023, there were no shares available for future issuance. The TeraImmune 2019 Plan was assumed by the Company through the Merger Agreement. Under the terms of the Merger Agreement, all options to purchase or acquire shares of TeraImmune held by continuing employees (as defined in the Merger Agreement) were assumed by the Company and converted into options to purchase shares of common stock and Series X Preferred Stock on the same terms and conditions as applied to such options and restricted stock awards immediately prior to the Acquisition.

Stock Options:

Options generally vest and become exercisable over two years and expire seven years from the date of grant. The weighted average grant-date fair value of the options awarded to employees during the six months ended June 30, 2023 was $0.24. Under the TeraImmune 2019 Plan, the fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions:

	June 30, 2023
Expected option life	5.6 years
Expected volatility	105%
Risk-free interest rate	4.38%
Expected dividend yield	—

The following table summarizes the stock option activity during the six months ended June 30, 2023:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2022	—	$ —	—
Granted	973,287	$ 2.37	5.6 years
Expired/forfeited/cancelled	—	$ —	
Balance, June 30, 2023	973,287	$ 2.37	5.6 years
Vested	202,384	$ 2.15	3.8 years
Vested and expected to vest	973,287	$ 2.37	5.6 years

Stock-Based Compensation Expense:

There was no stock-based compensation expense for the six months ended June 30, 2023.

As of June 30, 2023, there was $182 of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 2.7 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2023, there was no aggregate intrinsic value of the vested and unvested options.

(15) Retirement Plan

The Company has a voluntary 401(k) Savings Plan (the "401(k) Plan") in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the three months ended June 30, 2023 and 2022 were $27 and $32, respectively. Total Company contributions to the 401(k) plan for the six months ended June 30, 2023 and 2022 were $58 and $149, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the interim unaudited financial statements contained in Part I, Item 1 of this Quarterly Report, and the audited financial statements and notes thereto for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 23, 2023. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," the "Company" or "Baudax Bio" refer to Baudax Bio, Inc. and its consolidated subsidiaries.

Overview

We are a biotechnology company focused on developing T cell receptor, or TCR, therapies utilizing human regulatory T cells, or Tregs, as well as a portfolio of clinical stage Neuromuscular Blocking Agents, or NMBs, and an associated reversal agent. Our TCR Treg programs primarily focus on immune modulating therapies for orphan diseases or complications associated with such diseases, as well as the treatment of autoimmune disorders. We believe that our TCR Treg programs have the potential to provide valuable therapeutic options to patients suffering from diseases for which there are limited treatment options and significant unmet need, as well as to prescribers and payers in these markets.

On June 29, 2023, we acquired TeraImmune, Inc., or TeraImmune, a Delaware corporation. TeraImmune was a privately-held biotechnology company focused on discovery and development of novel Treg-based cell therapies for autoimmune diseases. TeraImmune's proprietary and patented technology platforms include a method for expansion of the Treg without losing its function and stability, as well as a method to target specific receptors including TCRs, Chimeric Antigen Receptors, or CARs and B cell Antigen Receptors, or BARs. TeraImmune has also in-licensed through an exclusive, sublicensable, royalty-bearing license, a patent family covering methods of producing T cell populations enriched for regulatory T cells and cell culture compositions from U.S. Department of Health and Human Services, as represented by National Institute of Allergy and Infectious Diseases of the National Institutes of Health. In addition, TeraImmune has developed Treg manufacturing procedures in accordance with regulatory guidance from the U.S. Food and Drug Administration, or the FDA.

In June 2022, TeraImmune's Investigational New Drug, or IND, application to commence clinical trials of a Factor VIII, or FVIII, TCR-Treg treatment for Hemophilia A with inhibitors was cleared by the FDA.

Tregs are designed to recognize and target certain cells through the engagement of target-specific receptors by peptide antigens presented on the surface of the target cell by the major histocompatibility complex. Our proprietary and patented technology platform consists of two approaches: (1) TREGable™, which involves the isolation of natural Tregs, and (2) TREGing™, which involves engineering effector T, or Teff, cells into antigen-specific Tregs. Each approach is intended to recognize and attack pathogens while avoiding an attack on healthy cells and tissues. The lead product candidate we acquired in the acquisition with TeraImmune, TI-168, is being developed for the treatment of Hemophilia A with inhibitors, which received IND clearance in 2022. We have in-licensed two patent families relating to TI-168, nucleic acids constructs encoding T cell receptors, methods of producing TI-168, immunosuppressive induced regulatory T cells from the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., or HJF, under two worldwide, exclusive, sublicensable royalty-bearing licenses. We also exclusively license a family of pending U.S. and foreign patent applications directed to immunosuppressive induced regulatory T cells and methods of producing these cells, which if issued would expire in 2041 subject to any applicable disclaimer or extensions.

We also hold exclusive global rights to two new molecular entities, which are centrally acting NMBs, BX1000, an intermediate duration of action NMB that recently completed a successful Phase II clinical trial, and BX2000, an ultra-short acting NMB currently undergoing a Phase I clinical trial. A proprietary blockade reversal agent, BX3000, is currently being evaluated in preclinical studies intended to support an IND filing in 2023. BX3000 is an agent that is expected to rapidly reverse BX1000 and BX2000 blockade. All three agents are licensed from Cornell University. We believe these agents, when an NMB and BX3000 are administered in succession, allow for a rapid onset of centrally acting neuromuscular blockade, followed by a rapid reversal of the neuromuscular blockade with BX3000. These novel agents have the potential to meaningfully reduce time to onset and reversal of blockade and improve the reliability of onset and offset of neuromuscular blockade. This can potentially reduce time in operating rooms or post operative units, resulting in potential clinical and cost advantages, as well as valuable cost savings for hospitals and ambulatory surgical centers and has the potential for an improved clinical profile in terms of safety.

In mid-2020, we launched our first commercial product, ANJESO, in the United States. ANJESO was the first and only 24-hour, intravenous, analgesia agent. ANJESO is a cyclooxygenase-2 preferential, non-steroidal anti-inflammatory drug, or NSAID, for the management of moderate to severe pain, which could be administered alone or in combination with other non-NSAID analgesics. We discontinued commercial sales of ANJESO in December 2022 and further withdrew its New Drug Application, or NDA, related to ANJESO in late March 2023.

Our costs have consisted primarily of expenses incurred in conducting our manufacturing and commercialization of ANJESO, which was discontinued in December 2022, as well as public company and personnel costs, clinical trials and preclinical studies, regulatory activities, and manufacturing costs for our NMB blocking and reversal agents. We expect to incur operating losses for at least the next

several years. We expect substantially all of our operating losses to result from costs incurred in connection with our development programs, including our clinical, nonclinical and formulation development, preclinical and manufacturing related activities. Our expenses over the next several years are expected to primarily relate to developing our product candidates. In addition, we may incur costs associated with the acquisition or in-license of products and successful commercialization of the acquired or in-licensed products.

Business Acquisition

On June 29, 2023, in accordance with the terms of an Agreement and Plan of Merger, or the Merger Agreement, we acquired 100% of the outstanding security interests of TeraImmune in a "stock-for-stock" transaction, or the Acquisition, whereby all TeraImmune outstanding equity interests were exchanged for a combination of shares of our common stock and shares of Series X Non-Voting Convertible Preferred Stock, or Series X Preferred Stock. Under the terms of the Merger Agreement, TeraImmune stockholders, or Target Stockholders, received (i) 1,212,185 shares of our common stock and (ii) 27,089.719 shares of Series X Preferred Stock, of which 314,282 of common stock and 7,024 of preferred stock are classified as escrow shares at Closing. In addition, all outstanding options to purchase or acquire shares of TeraImmune common stock were assumed by us and converted into restricted stock awards and options to purchase shares of common stock and Series X Preferred Stock on the same terms and conditions as applied to such options and restricted stock awards immediately prior to the Acquisition. Subject to shareholder approval of the conversion and certain beneficial ownership limitations set by each holders, each share of Series X Preferred Stock will automatically convert into 1,000 shares of common stock. On a pro forma basis and based upon the number of shares of our common stock and preferred stock issued in the Acquisition, our shareholders immediately prior to the Acquisition will own approximately 18% of the combined company (on an as-converted, fully-diluted basis and excluding certain out-of-the-money warrants held by our shareholders) immediately after these transactions. The Acquisition was unanimously approved by our Board of Directors and the Board of Directors of TeraImmune. The closing of the transaction was not subject to the approval of our shareholders.

Pursuant to the Merger Agreement, we agreed to hold a special meeting of shareholders, or the Special Meeting, to submit certain matters to our shareholders for their consideration, including: (i) the approval of the conversion of the Series X Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a), or the Conversion Proposal, and (ii) the approval to effect a reverse stock split of all of our issued and outstanding shares of common stock, or the Reverse Stock Split Proposal, together with the Conversion Proposal, the "Merger Agreement Meeting Proposals". In connection with these matters, we filed a preliminary proxy statement and other relevant materials with the Securities and Exchange Commission, or SEC on July 31, 2023.

ANJESO Transfer Agreement

In March 2023, we entered into an Asset Transfer Agreement with Alkermes Pharma Ireland Limited, or Alkermes, or the Transfer Agreement. Under the terms of the Transfer Agreement, we transferred the rights to certain patents, trademarks, equipment, data and other rights related to ANJESO, or the Assets to Alkermes. We also withdrew the New Drug Application, or NDA, related to ANJESO and agreed, if elected by Alkermes at a later date, to transfer such withdrawn NDA to Alkermes at no additional cost.

2022 Reduction in Force

Due to our cash position, in March 2022, we implemented a reduction in workforce by approximately 17 employees related to our continuing operations. The reorganization was substantially completed by the end of the second quarter of 2022 and approximately $1.7 million of charges were incurred for severance and other related costs. The reduction in force was designed to substantially reduce our operational expenses and conserve cash resources.

Discontinued Operation

Upon executing the Transfer Agreement, we met the criteria for discontinued operations related to our commercial business. Accordingly, the accompanying consolidated financial statements for all periods presented reflect this business as a discontinued operation. Discontinued operations include results of our commercial business except for certain corporate overhead costs, which are included in continuing operations. See Note 4 to the Consolidated Financial Statements included in this Quarterly Report for additional information.

Financial Overview

Revenue

We sold ANJESO in the U.S. through a single third-party logistics provider, or 3PL, which took title to and control of the goods and was considered our customer. We recognized revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtained control of the product. The transaction price that was recognized as revenue for products

included an estimate of variable consideration for reserves, which result from discounts, returns, chargebacks, rebates and other allowances that were offered within contracts between us and our end-user customers, wholesalers, group purchasing organizations and other indirect customers. In December 2022, we discontinued the commercialization of ANJESO and the majority of expenses associated with the discontinuation were incurred by the end of the first quarter of 2023.

Cost of Sales

Historically, cost of sales included product costs, manufacturing costs, transportation and freight, royalty expense, qualification costs for a secondary manufacturing suite and indirect overhead costs associated with the manufacturing and distribution of ANJESO including supply chain and quality personnel costs. Cost of sales also included period costs related to certain manufacturing services and inventory adjustment charges. We discontinued commercialization of ANJESO in December 2022. We believe there is very modest inventory held at the wholesaler level and have notified wholesalers through our 3PL that we will accept product returns until June 30, 2023, which have been recorded as of June 30, 2023.

Research and Development Expenses

Research and development expenses have consisted primarily of costs incurred in connection with the NMB portfolio and in previous years, the FDA required pediatric development of ANJESO activities. These expenses consist primarily of:

- expenses incurred under agreements with investigative sites, consultants and other service providers that conduct or support our clinical and pre-clinical trials;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services;
- costs related to facilities, depreciation and other allocated expenses;
- costs associated with regulatory activities and responses to the FDA; and
- salaries and related costs for personnel in research and development and pre-commercial regulatory functions.

The majority of our external research and development costs have related to clinical trials, manufacturing of drug supply for pre-commercial products, analysis and testing of product candidates and patent costs. We expense costs related to clinical inventory and pre-commercial inventory until we receive approval from the FDA to market a product, at which time we commence capitalization of costs relating to that product to inventory. Costs related to facilities, depreciation and support are not charged to specific programs. Subsequent to regulatory approval of ANJESO and prior to the withdrawal of the NDA, we allocated or recategorized certain personnel and overhead expenses related to medical affairs, supply chain, quality and regulatory support functions that had previously been recorded within research and development, to cost of sales or selling, general and administrative expenses in support of the commercialization of ANJESO. Pre-commercial activities directly utilizing personnel and overhead expenses from the medical affairs, supply chain, quality and regulatory support function continue to be recorded within research and development.

The development of our other product candidates is highly uncertain and subject to a number of risks, including, but not limited to:

- the costs, timing and outcome of regulatory review of a product candidate;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the emergence of competing technologies and products, including obtaining and maintaining patent protections, and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the sections titled “Risk Factors” of our 2022 Annual Report and this Quarterly Report.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we will assess our product candidate's commercial potential and our available capital resources. As a result of these uncertainties surrounding the timing and outcome of any approval, we are currently unable to estimate precisely when, if ever, any of our product candidates will generate revenues and cash flows.

We expect our research and development costs to relate to the development and commercialization scale-up of our Treg-based cell therapy portfolio and NMB product candidate portfolio. We may elect to seek collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

Selling, General and Administrative Expenses

Selling, general and administrative expenses have historically consisted of sales and marketing expenses related to ANJESO and general and administrative expenses.

Sales and marketing expenses primarily consisted of compensation and benefits for our sales force and personnel that supported our sales and marketing efforts as well as third party consulting costs for the promotion and sale of ANJESO. In addition, sales and marketing expenses included expenses related to communicating the clinical and economic benefits of ANJESO and educational programs for our indirect customers.

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and information technology functions, and additionally in the prior year, the commercial portion of the medical affairs and regulatory functions. General and administrative expenses also include public company costs, directors and officer's insurance, professional fees for legal, including patent-related expenses, consulting, auditing, and tax services.

Our general and administrative expenses decreased in the quarter ended June 30, 2023 as a result of the reduction in personnel in 2022, consulting and public company costs, and we expect no future selling and commercial costs at this time.

Interest Expense

Interest expense for the periods presented primarily includes interest expense incurred on our Credit Agreement with MAM Eagle Lender, the amortization of related financing costs, and in the current year the resulting loss on extinguishment of debt from Amendment No. 5 of the MAM lender agreement.

Income Taxation

We maintained a valuation allowance against our deferred tax assets as of June 30, 2023 and December 31, 2022.

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,	
	2023	2022
	(amounts in thousands)	
Operating expenses:		
Research and development	$ 1,779	$ 879
General and administrative	2,254	2,898
Change in fair value of warrants and derivatives	2,870	(1)
Change in contingent consideration valuation	142	—
Total operating expenses	7,045	3,776
Operating loss from continuing operations	(7,045)	(3,776)
Other expense:		
Other expense, net	(256)	(569)
Net loss from continuing operations	(7,301)	(4,345)
Loss on discontinued operation	(74)	(3,186)
Net loss	$ (7,375)	$ (7,531)

Research and Development. Our research and development expenses were $1.8 million and $0.9 million for the three months ended June 30, 2023 and 2022, respectively. The increase of $0.9 million was a result of an increase in clinical trials costs associated with our NMB portfolio.

General and Administrative. Our general and administrative expenses were $2.3 million and $2.9 million for the three months ended June 30, 2023 and 2022, respectively. The decrease of $0.6 million was primarily a result of a reduction in personnel costs of $0.6 million and a decrease in consulting expenses of $0.3 million, partially offset by an increase in public company costs of $0.3 million.

Change in Fair Value of Warrants and Derivatives. Our derivative liability is our obligation to issue shares of our Series X Preferred Stock and common stock, at the option of the investor in TIT and is revalued at each reporting period. The fair value increased by $2.9 million for the three months ended June 30, 2023 as a result of an increase in our share price.

Change in Contingent Consideration valuation. Our contingent consideration is related to shares held in escrow as a result of the Merger and is revalued at each reporting period. The fair value increased by $0.1 million for the three months ended June 30, 2023 as a result of an increase in our share price.

Other Expense, net. Other expense was $0.3 million and $0.6 million for the three months ended June 30, 2023 and 2022, respectively. The decrease in other expense of $0.3 million was primarily related to a decrease of $0.2 million in the amortization of financing costs and a decrease of $0.1 million in interest expense related to our Credit Agreement with MAM Eagle Lender due to the reduction in principal balance.

Loss on discontinued operations. Loss from discontinued operations for the three months ended June 30, 2023 and 2022 was $0.1 million and $3.2 million, respectively, which relates to our discontinued commercial business of ANJESO. The decrease in loss from the discontinued operation of $3.1 million was primarily the result of a decrease of $1.3 million in expense related to the change in fair value of contingent consideration, an decrease of $1.2 million in reduced selling expenses due to the discontinuation of commercialization of ANJESO, and a decrease of $0.6 million in amortization expense.

Comparison of the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,	
	2023	2022
	(amounts in thousands)	
Operating expenses:		
Research and development	4,696	1,573
General and administrative	4,025	9,832
Change in fair value of warrants and derivatives	2,870	(6)
Change in contingent consideration valuation	142	—
Total operating expenses	11,733	11,399
Operating loss from continuing operations	(11,733)	(11,399)
Other expense:		
Other expense, net	(2,954)	(1,140)
Net loss from continuing operations	(14,687)	(12,539)
Income (loss) on discontinued operation	18,716	(7,801)
Net income (loss)	$ 4,029	$ (20,340)

Research and Development. Our research and development expenses were $4.7 million and $1.6 million for the six months ended June 30, 2023 and 2022, respectively. The increase of $3.1 million was primarily due to an increase in operational expenses associated with our NMB program, including clinical and preclinical trials costs, of $2.8 million and an increase in general expenses, including consulting and other outside service expenses, of $0.3 million.

General and Administrative. Our general and administrative expenses were $4.0 million and $9.8 million for the six months ended June 30, 2023 and 2022, respectively. The decrease of $5.8 million was primarily a result of a reduction in personnel costs of $4.1 million, a decrease in consulting expenses of $0.9 million, a decrease in public company costs of $0.4 million, a decrease of $0.2 million in patent legal expenses and a decrease of $0.2 million in other costs.

Change in Fair Value of Warrants and Derivatives. Our derivative liability is our obligation to issue shares of our Series X Preferred Stock and common stock, at the option of the investor in TIT and is revalued at each reporting period. The fair value increased by $2.9 million for the six months ended June 30, 2023 as a result of an increase in our share price.

Change in Contingent Consideration valuation. Our contingent consideration is related to shares held in escrow as a result of the Merger and is revalued at each reporting period. The fair value increased by $0.1 million for the six months ended June 30, 2023 as a result of an increase in our share price.

Other Expense, net. Other expense was $3.0 million and $1.1 million for the six months ended June 30, 2023 and 2022, respectively. The increase in other expense of $1.9 million was primarily due to the loss on extinguishment of debt as a result of the fifth amendment to the MAM credit agreement of $2.1 million, partially offset by a decrease in financing expenses also related to our MAM credit agreement of $0.2 million.

Income (loss) on discontinued operations. Income from discontinued operations for the six months ended June 30, 2023 was $18.7 million, compared to a loss from discontinued operation for the six months ended June 30, 2022 of $7.8 million, an increase in income of $26.5 million, which primarily relates to our discontinued commercial business of ANJESO. The increase in income from the discontinued operation was primarily the result of a decrease of $17.4 million in expense related to the change in fair value of contingent consideration, a decrease of $8.4 million in reduced selling expenses due to the discontinuation of commercialization of ANJESO, and a decrease of $1.3 million in amortization expense, partially offset by an increase of $0.6 million in expense related to the impairment of property and equipment in 2023 related to ANJESO.

Liquidity and Capital Resources

As of June 30, 2023, we had $1.4 million in cash and cash equivalents.

We anticipate that our principal uses of cash in the future will be primarily to fund our operations, pipeline development activities, working capital needs, and other general corporate purposes.

We expect to seek additional funding to sustain our future operations and while we have successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on our available cash as of June 30, 2023, we will need to raise additional capital in the next twelve months to continue as a going concern.

On May 1, 2023 we closed a best efforts public offering of: (i) 1,326,175 shares of our common stock, par value $0.01 per share and accompanying Series A-5 warrants to purchase 1,326,175 shares of Common stock and Series A-6 warrants to purchase 1,326,175 shares of common stock, at a combined public offering price of $1.15 per share and accompanying Series A warrants and (ii) Series D pre-funded warrants to purchase 2,152,087 shares of common stock and accompanying Series A-5 warrants to purchase 2,152,087 shares of common stock and Series A-6 warrants to purchase 2,152,087 shares of common stock at a combined public offering price of $1.14 per Series D pre-funded warrant and accompanying Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series D pre-funded warrant. The Series A warrants have an exercise price of $1.15 per share of common stock. The Series A-5 warrants are exercisable upon issuance and expire on May 1, 2028. The Series A-6 warrants are exercisable upon issuance and expire on November 1, 2024. Subject to certain ownership limitations described in the Series D pre-funded warrants, the Series D pre-funded warrants were immediately exercisable and were fully exercised at a nominal consideration of $0.01 per share of common stock shortly after closing. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the offering, we paid the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. We also issued to designees of the placement agent warrants to purchase up to 208,696 shares of common stock. These warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $1.4375 per share and expire on April 26, 2028. Net proceeds after deducting underwriting discounts and commissions and offering expenses, was $3.3 million.

On December 6, 2022 we closed a best efforts public offering of: (i) 54,787 shares of our common stock, par value $0.01 per share and accompanying Series A-3 warrants to purchase 54,787 shares of common stock and Series A-4 warrants to purchase 54,787 shares of common stock, at a combined public offering price of $4.795 per share and accompanying series A warrants and (ii) series C pre-funded warrants to purchase 988,000 shares of common stock and accompanying series A-3 warrants to purchase 988,000 shares of common stock and series A-4 warrants to purchase 988,000 shares of common stock at a combined public offering price of $4.785 per series C pre-funded warrant and accompanying series A warrants, which was equal to the public offering price per share of common stock and accompanying series A warrants less the $0.01 per share exercise price of each such series C pre-funded warrant. The series A warrants have an exercise price of $4.50 per share of common stock. The series A-3 warrants are exercisable upon issuance and expire on December 6, 2027. The series A-4 warrants are exercisable upon issuance and expire on January 8, 2024. The exercise price of the series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A Warrants. The Series C prefunded warrants have been exercised in full as of December 31, 2022. As compensation to H.C. Wainwright & Co., LLC as the exclusive placement agent in connection with the offering, we paid the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. We also issued to designees of the placement agent warrants to purchase up to 62,567 shares of common stock. The Placement Agent Warrants have substantially the same terms as the series A warrants, except that the placement agent warrants have an exercise price equal to $5.99375 per share and expire on December 2, 2027. Net proceeds after deducting underwriting discounts and commissions and offering expenses, was $4.0 million.

On September 1, 2022, we closed a best efforts public offering of: (i) 188,872 shares of its common stock, par value $0.01 per share and accompanying Series A-1 warrants to purchase 188,872 shares of Common stock and Series A-2 warrants, and together with the Series A-1 warrants to purchase 188,872 shares of Common Stock, at a combined public offering price of $21.00 per share and Series A warrants and (ii) Series B pre-funded warrants to purchase 106,607 shares of Common Stock and accompanying Series A-1 warrants to purchase 106,607 shares of Common Stock and Series A-2 warrants to purchase 106,607 shares of Common stock at a combined public offering price of $20.60 per Series B pre-funded warrant and Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series B pre-funded warrant. The Series A warrants have an exercise price of $21.00 per share of Common Stock. The Series A-1 warrants are exercisable upon issuance and will expire five years from the date of issuance. The Series A-2 warrants are exercisable upon issuance and will expire thirteen months from the date of issuance. The exercise price of the Series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A warrants. Subject to certain ownership limitations, the Series B pre-funded warrants were immediately exercisable and were exercised at a nominal consideration of $0.01 per share of Common Stock upon the closing of the transaction. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the Offering, we paid a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering, and reimbursement of certain expenses and legal fees. We also issued to designees of the placement agent warrants to purchase up to 17,728 shares of common stock. The placement agent warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $26.25 per share and expire on August 29, 2027. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was $5.0 million.

On May 17, 2022, we closed a registered direct offering of 41,152 shares of our common stock, par value $0.01 per share, and in a concurrent private placements, warrants exercisable for up to an aggregate of 41,152 shares of common stock at a combined offering price of $48.60 per share and associated warrant. The warrants have an exercise price of $43.60 per share. Each warrant is exercisable for one share of common stock and was exercisable immediately upon issuance. The warrants have a term of five years from the issuance date. As compensation to H.C. Wainwright & Co., LLC as placement agent in connection with the offering, we agreed to pay to the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering and certain expenses. We also issued to designees of the placement agent warrants to purchase up to 6.0% of the aggregate number of shares of common stock sold in the transactions, or warrants to purchase up to 2,469 shares of common stock. The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the offering price per share (or $60.75 per share). The placement agent warrants will expire on May 17, 2027. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was $1.7 million.

On March 1, 2022, we closed an underwritten public offering of 45,791 shares of common stock, pre-funded warrants to purchase 41,929 shares of common stock at an exercise price of $0.01 per share and warrants to purchase 87,719 shares of common stock at an exercise price of $130.00 per share, as well as up to 13,158 additional shares of common stock and/or additional warrants to purchase up to 13,158 shares of common stock which may be purchased pursuant to a 30-day option to purchase additional securities granted to H.C. Wainwright & Co., LLC (the "Underwriter") by us. The public offering price for each share of common stock and accompanying warrant to purchase one share of common stock was $114.00, and the public offering price for each pre-funded warrant and accompanying warrant was $113.60. As compensation to the Underwriter, we agreed to pay to the Underwriter a cash fee of 7.0% of the gross proceeds, plus a cash management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. We also issued to designees of the Underwriter warrants to purchase 5,263 shares of common stock at an exercise price of $142.50 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 2,847 warrants. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was $8.8 million.

On May 29, 2020, we entered in a $50.0 million Credit Agreement with MAM Eagle Lender, pursuant to which we have drawn $10.0 million as of the date of this Quarterly Report and may draw upon four additional tranches of term loans. The Tranche Two Loans in an amount not to exceed $5.0 million may be drawn upon on or before August 29, 2021 provided that we generate at least $5.0 million in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Two Loans are funded. The Tranche Two Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Three Loans, Tranche Four Loans, or Tranche Five Loans, as applicable, provided that the Tranche Two Loans may not be drawn more than once. The Tranche Three Loans in an amount not to exceed $5.0 million may be drawn upon on or before November 29, 2021 provided that we generate at least $10.0 million in net revenue in the three consecutive calendar months immediately preceding such date such Tranche Three Loans are funded. The Tranche Three Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Four Loans or Tranche Five Loans, as applicable, provided that the Tranche Three Loans may not be drawn more than once. The Tranche Four Loans in an amount not to exceed $10.0 million may be drawn upon, subject to the consent of the Lenders, on or before August 29, 2022 provided that we generate at least $20.0 million in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Four Loans are funded. The Tranche Four Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Five Loans provided that the Tranche Four Loans may not be drawn more than once. The Tranche Five Loans in an amount not to exceed $20.0 million may be drawn upon, subject to the consent of the Lenders, on or before March 1, 2023 provided that we generate at least $100.0 million in net revenue in the twelve consecutive calendar months immediately preceding the date such Tranche Five Loans are funded.

On August 1, 2022, we entered into Amendment No. 1 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the lenders waived any default under the credit agreement (including the imposition

of a default interest rate with respect to the default) resulting from our failure to comply with the minimum cash covenant, or the Minimum Liquidity Covenant, which requires us to maintain at least $5.0 million in a liquidity account. In addition, the Amendment, among other items, (i) provides that 30% of any cash proceeds received by us from certain potential strategic licensing transactions shall be used to prepay amounts outstanding under the credit agreement; and (ii) decreases the amount of cash we are required to maintain pursuant to the Minimum Liquidity Covenant to $3.0 million for a period beginning on August 1, 2022, and ending on August 31, 2022, at which point the amount required pursuant to the Minimum Liquidity Covenant shall increase to $5.0 million.

On October 24, 2022, we entered into Amendment No. 2 and Waiver to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the Credit Agreement is amended such that we must repay the principal thereunder (i) on the first business day of each month until the Interest Payment Date on December 1, 2022, in equal monthly installments of principal based on an amortization schedule of 36 months, (ii) an additional payment of principal in the amount of $0.3 million prior to December 31, 2022 and (iii) commencing on the Interest Payment Date on January 2, 2023 and on each Interest Payment Date thereafter until the obligations have been repaid in full, the principal amount of $0.5 million. In addition, the amendment decreases the minimum cash covenant we are required to maintain under the Credit Agreement to (i) $3.0 million for the period beginning on October 1, 2022, and ending on November 30, 2022, (ii) $4.5 million for the period beginning on December 1, 2022, and ending on February 28, 2023, and (iii) $4.0 million from and after March 1, 2023. Further, we have agreed that prior to December 31, 2022, we shall not, without the prior written consent of the Lenders, make or permit any payment under its agreements with Alkermes. In consideration for the amendment, we paid the Agent an amendment fee of $0.01 million and the Lender an amendment fee of $0.2 million.

On December 1, 2022, we entered into Amendment No. 3 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the amendment decreases the minimum cash covenant we are required to maintain under the credit agreement to (a) from October 1, 2022 to December 6, 2022 to not be less than $3.0 million at any time, (b) from December 7, 2022 to February 28, 2023 to not be less than $4.5 million, and (c) from and after March 1, 2023 to not be less than $4.0 million.

In January 2023, we entered into Amendment No. 4 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the credit agreement was amended such that we must make (i) a payment of principal in the amount of $0.5 million on January 3, 2023, (ii) a payment of principal in the amount of $0.3 million on February 1, 2023 and March 1, 2023, and (iii) on the interest payment date on April 3, 2023 and on each interest payment date thereafter until the obligations are repaid in full, a payment in the principal amount of $0.5 million. In addition, the amendment decreases the minimum cash covenant we are required to maintain under the credit agreement, or the Minimum Liquidity Covenant, to (i) $3.0 million for the period beginning on October 1, 2022, and ending on December 6, 2022, (ii) $4.5 million for the period beginning on December 7, 2022, and ending on January 10, 2023, (iii) $2.225 million for the period beginning on January 11, 2023, and ending on February 28, 2023, and (iv) $3.0 million from and after March 1, 2023. Further, we have agreed that prior to April 30, 2023, we will not, without the prior written consent of MAM Eagle Lender, make or permit any payment under our agreements with Alkermes.

On March 29, 2023, we entered into Amendment No. 5 and Consent to Credit Agreement whereby MAM Eagle Lender consented to the transactions contemplated by the Transfer Agreement (as defined above) and agreed to release and discharge any liens granted or held by the lenders in respect of the assets discussed in the Transfer Agreement. The parties also agreed to, among other things, amend the minimum liquidity covenants under the Credit Agreement to require that we maintain $2.5 million of liquidity at all times.

In connection with the Acquisition, we entered into a Forbearance Agreement, dated as of June 29, 2023, by and among us, the Lenders and the Agent, solely in its capacity as administrative and collateral agent for the Lenders, pursuant to which the Lenders agreed to forbear their rights to exercise any rights and remedies with respect to any default under the Credit Agreement, resulting from the Acquisition, for a period of up to 30 days following the closing of the Acquisition. On July 30, 2023, the parties amended the Forbearance Agreement to extend such deadline until October 31, 2023.

Sources and Uses of Cash

Cash used in operations was $7.3 million and $10.0 million for the six months ended June 30, 2023 and 2022, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, depreciation, loss on extinguishment of debt, and changes in warrant valuations, as well as changes in operating assets and liabilities.

Cash provided by investing activities was $0.1 for the six months ended June 30, 2023 and was attributable to the acquisition of TeraImmune. There was no cash provided by investing activities for the six months ended June 30, 2022.

There was $4.1 million of net cash provided by financing activities in the six months ended June 30, 2023 consisting of proceeds of $4.3 million from warrant exercises and proceeds of $3.5 million from a public offering of common stock and warrants, partially offset by $3.5 million in long-term debt principal payments and $0.2 million in payments of deferred financing costs. There was $10.5 million of net cash provided by financing activities for the six months ended June 30, 2022 consisting primarily of net proceeds of $8.9 million from public offerings of common stock and warrants and $1.8 million of net proceeds from a registered direct offering of common stock and concurrent private placement of warrants, partially offset by a payment on long-term debt of $0.2 million.

Cash used in operations from discontinued operations was $0.8 million and $10.1 million for the six months ended June 30, 2023 and 2022, respectively, which represents our operating losses from discontinued operation less our non-cash items including: stock-based compensation, depreciation, amortization, changes in fair value of contingent consideration, and impairment losses on property and equipment and intangible asset, as well as changes in operating assets and liabilities.

There was no significant cash used in investing activities from discontinued operation for the six months ended June 30, 2023 and 2022.

There was no cash used in financing activities from discontinued operation in the six months ended June 30, 2023. There was $1.0 million of cash used in financing activities from discontinued operation in the six months ended June 30, 2022 attributable to the payment of contingent consideration of $1.0 million.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- our relationships with third parties, licensors, collaborators, and our employees;
- our ability to execute our strategic priorities;
- our ability to fund our continuing operations and successfully integrate TeraImmune's operations;
- the scope, progress, results, and costs of development for our product candidates;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our product candidates;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- our ability to raise additional funds through equity or debt financings or the sale of certain assets;
- our ability to regain compliance with the listing requirements of the Nasdaq Capital Market;
- our ability to comply with our debt covenants;
- the extent to which holders of our warrants exercise their warrants resulting in the payment of cash proceeds to us;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Separation and changes in tax laws.

We may use existing cash and cash equivalents on hand, debt, equity financing, sale of assets or out-licensing revenue or a combination thereof to fund our operations or product acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The table below reflects our contractual commitments as of June 30, 2023:

	Payments Due by Period (in 000s)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Debt Obligations (1):					
Credit Agreement	$ 4,256	$ 4,256	$ —	$ —	$ —
Interest and Fees on Credit Agreement	861	861	—	—	—
Convertible Bond Payable	1,000	1,000	—	—	—
Interest on Bond Payable	239	239	—	—	—
Purchase Obligations (2):	$ 64	$ 64	$ —	$ —	$ —
Operating Leases (3)	5,094	680	1,409	1,809	1,196
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4)	16,395	80	315	—	—
Employment Agreements (5)	1,067	758	309	—	—
Total Contractual Obligations	$ 28,976	$ 7,938	$ 2,033	$ 1,809	$ 1,196

(1)Debt obligations consist of principal, an exit fee of 2.5% of that principal, interest on the $4.3 million outstanding term loan under our Credit Agreement and the unpaid portion of the Amendment No. 5 fee. Debt obligations also consists of a principal balance of $1,000 in convertible bond payable, accrued interest at a rate of 5% per annum during the period from April 8, 2022 to the maturity date of November 30, 2022, and a default interest penalty of 20% on the defaulted balance as of November 30, 2022. In accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 11 to the Consolidated Financial Statements included in this Quarterly Report.

(2)These obligations consist of cancelable and non-cancelable purchase commitments related to development activities and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12(b) to the Consolidated Financial Statements included in this Quarterly Report.

(3)We are party to certain operating leases for the leased space in (i) Malvern, Pennsylvania (ii) Dublin, Ireland, and (iii) Germantown, Maryland, for which the minimum lease payments are presented. See Note 9 to the Consolidated Financial Statements included in this Quarterly Report.

(4)We license NMBs, from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments totaling a maximum of $16,000 across three compounds because they are dependent on the type and complexity of regulatory filing approvals in the U.S. and Europe and the number of product candidates approved, which have not been established, and as such are only included in the total. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See 12(a) to the Consolidated Financial Statements included in this Quarterly Report.

(5)We have entered into employment agreements with our named executive officers. As of June 30, 2023, this employment agreement provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through September 2024. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12(c) to the Consolidated Financial Statements included in this Quarterly Report.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are disclosed in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our 2022 Annual Report. In the six months ended June 30, 2023, there were no significant changes to the application of critical accounting policies previously disclosed in our 2022 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2023. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to a material weakness in our internal control over financial reporting in connection with the implementation of purchase price accounting principles related to the Acquisition of TeraImmune. Specifically, we were required to make a number of post-closing adjustments to our consolidated financial statements as a result of the implementation of certain purchase price accounting principles not previously implemented prior to the close of the quarter. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does management believe that it had any effect on the accuracy of our financial statements for the current reporting period. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Remediation Plan

Management and our Board of Directors are actively engaged in implementing a remediation plan to address the material weakness over the implementation of purchase price accounting related to the Acquisition of TeraImmune. We are enhancing and implementing new processes, controls, and systems to strengthen our internal control over financial reporting. Additionally, we intend to seek additional internal and external resources to aid in our mitigation and increase the level of review over financial reporting.

Changes in Internal Control over Financial Reporting

On June 29, 2023, we completed the Acquisition. Under guidelines established by the SEC, companies are permitted to exclude acquisitions from their assessment of internal control over financial reporting during the first year of an acquisition while integrating the acquired company. Based on those guidelines, our assessment of the effectiveness of our internal control over financial reporting will exclude TeraImmune. We are in the process of integrating TeraImmune into our system of internal control over financial reporting.

Other than as set forth above, there has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

Other than what is set forth below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

If we are unable to meet the initial listing standards of Nasdaq by November 13, 2023, or otherwise regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise capital.

The listing standards of the Nasdaq Stock Market LLC provide, among other things, that a company, in order to qualify for continued listing, must (i) maintain shareholders' equity of at least $2,500,000 pursuant to Nasdaq Listing Rule 5550(b)(1), or Rule 5550(b)(1), and (ii) maintain a minimum bid price of at least $1.00 per share pursuant to Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2).

On November 18, 2022, the Nasdaq Listing Qualifications Department, or the Staff, informed us that we did not comply with Rule 5550(b)(1). The Staff granted our request for an extension until May 15, 2023, to comply with Rule 5550(b)(1). On May 17, 2023, we received a delist determination letter from the Staff advising us that the Staff had determined that we did not meet the terms of such extension. We requested an appeal of the Staff's determination and submitted a hearing request to the Nasdaq Hearings Panel ("Panel"), which request stayed any delisting action by the Staff at least until the hearing process concludes and any extension granted by the Panel expires.

On June 9, 2023, we received a deficiency letter from the Staff notifying us that we are not in compliance with Rule 5550(a)(2) and because we effected two reverse stock splits over the previous two-year period with a cumulative ratio of 250 shares or more to one, we are not eligible for any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A). Our noncompliance with Rule 5550(a)(2) serves as an additional basis for delisting of our securities from the Nasdaq and the Panel will consider this matter in rendering a determination regarding the our continued listing on the Nasdaq. On June 29, 2023, our hearing with the Panel was held and we submitted our plan for compliance to the Panel. On July 24, 2023, we received a letter from the Staff, or the Hearing Decision, notifying us of its decision to grant our request to continue our listing on Nasdaq on a conditional basis, subject to, among other things, our ability to demonstrate compliance with the Nasdaq initial listing requirements by or before November 13, 2023. There can be no assurance that we will meet the conditions set forth by the Staff in the Hearing Decision, or that we will be able to regain compliance with such applicable Nasdaq listing requirements.

Furthermore, we believe that our acquisition of TeraImmune will, upon shareholder approval of the conversion of the Series X Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a), be considered a "change of control" transaction under Nasdaq rules. As such, the Company must meet Nasdaq's initial listing requirements. Accordingly, the Company must meet all the requirements set forth in Nasdaq Listing Rule 5505(a) and at least one of the standards set forth in Nasdaq Listing Rule 5505(b).

The listing standards of Nasdaq Listing Rule 5505(a) require the Company to have, among other things:

- a minimum bid price that is greater than or equal to $4.00 per share;
- at least 1,000,000 unrestricted publicly held shares;
- at least 300 round-lot holders, and at least 50% of such round lot holders must each hold unrestricted securities with a market value of at least $2,500;
- at least three registered and active market makers; and
- a minimum average daily trading volume of 2,000 shares over the 30 trading day period prior to listing, with trading occurring on more than half of those 30 days, unless such security is listed on Nasdaq in connection with a firm commitment underwritten public offering of at least $4 million.

The Company must also satisfy at least one of the following Nasdaq Listing Rule 5505(b) requirements:

- shareholders' equity of at least $5 million, a market value of unrestricted publicly held shares of at least $15 million, and two years of operating history;

•a market value of listed securities of at least $50 million, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $15 million; or

•net income from continuing operations of $750,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years, shareholders' equity of at least $4 million, and a market value of unrestricted publicly held shares of at least $5 million.

There is no assurance that we will be able to meet Nasdaq's initial listing requirements or comply with the requisite Nasdaq requirements to maintain our listing of common stock on Nasdaq. If Nasdaq delists our securities from trading on its exchange and we are not able to list our securities on Nasdaq or any other national securities exchange, we could face significant material adverse consequences, including:

•a limited availability of market quotations for our common stock;

•reduced liquidity for our common stock;

•a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for its securities;

•a limited amount of news and analyst coverage for us;

•a decreased ability to issue additional securities or obtain additional financing in the future; and

•the incurring of additional costs under state blue sky laws in connection with any sales of our securities.

If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. In the event our common stock is delisted from Nasdaq, we may not be able to list our common stock on another national securities exchange or obtain quotation on an over-the counter quotation system.

Our business has incurred significant losses since our inception, and we may continue to incur significant losses for the foreseeable future. We may never achieve profitability.

Our business has incurred operating losses due to costs incurred in connection with our research and development activities, general and administrative expenses, and commercialization expenses associated with our operations. Our net losses from continuing operations for the quarters ended June 30, 2023 and 2022 were $14.7 million and $12.5 million, respectively. As of June 30, 2023, we had an accumulated deficit of $186.9 million. We launched ANJESO, our first commercial product, in mid-2020, but we have not generated significant revenue from sales of ANJESO, and in December 2022, we announced the discontinuation of the sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture. For the years ended December 31, 2022 and 2021, net product revenue was $1.3 million and $1.1 million, respectively, related to sales of ANJESO in the U.S. Our product candidate pipeline includes early-stage product candidates, including a T cell-based immunotherapy for the treatment of Hemophilia A with inhibitors, two NMBs and a related proprietary chemical reversal agent. If our product candidates are not successfully developed and approved, we may never generate any new revenue. All of our product candidates will require the expenditure of substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin realizing product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and potentially commercialize any of our product candidates, if approved, and seek to identify, assess, acquire, in-license, or develop additional product candidates. Our prior losses, combined with expected future losses, have had and will continue to have a negative effect on our shareholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. We anticipate that our expenses will increase substantially if, and as, we:

•continue clinical development of TI-168, BX1000 and BX2000 and preclinical development of BX3000, which is currently being evaluated in preclinical studies intended to support an IND filing in the last quarter of 2023, and our other preclinical T cell-based immunotherapies;

•seek to discover and develop additional product candidates;

•seek regulatory approvals for any of our product candidates that successfully complete clinical trials;

•maintain, expand, protect, and enforce our intellectual property portfolio;

•acquire or in-license other product candidates and technologies; and

•increase our employee headcount and related expenses to support these activities.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to generate revenue or achieve or maintain profitability.

We may be unsuccessful in obtaining a waiver or amendment to our Credit Agreement with respect to any existing events of default thereunder. The failure to obtain such a waiver or amendment, or otherwise cure any event of default under our Credit Agreement, could allow the lender to take enforcement action against the Company or certain of its assets, including accelerating the loans and other obligations under the Credit Agreement and taking any other remedial actions permitted under the Credit Agreement or applicable law, which would have a material adverse effect on our business, financial condition and results of operations and could require us to curtail or cease operations.

On May 29, 2020, we entered into the Credit Agreement. In connection with the Acquisition, we entered the Forbearance Agreement, pursuant to which Agent and Lender agreed to forbear form exercising their rights and remedies with respect to certain events of default under the Credit Agreement until October 31, 2023.

There can be no assurance that Agent and Lender will provide us with a waiver of any events of default or agree to amend the Credit Agreement in a timely manner, or on acceptable terms, if at all to the extent any events of default have occurred and are continuing under the Credit Agreement. If we do not obtain an amendment or waiver of such events of default under the Credit Agreement, if any future events of default occur and are continuing or if the Lenders take the position that we have not complied with the terms of the Forbearance Agreement, there can be no assurance that the Lenders will not take action to collect payment of our debt or dispose of collateral securing the obligations under the Credit Agreement, which would harm our business, financial condition and results of operations and could require us to curtail or cease operations.

Our internal controls over financial reporting could fail to prevent or detect misstatements or have material weaknesses.

Our internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Any failure to maintain effective internal controls or to timely effect any necessary improvement or remediate any lapse in our internal control and disclosure controls could, among other things, result in losses from fraud or error, require significant resources and divert management's attention, harm our reputation, causing investors to lose confidence in our reported financial and other information, and expose use to legal or regulatory proceedings, all of which could have a material adverse effect on our financial condition, results of operations and cash flows.

As of June 30, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to a material weakness in our internal control over financial reporting in connection with the implementation of purchase price accounting principles related to the Acquisition of TeraImmune. Management is taking steps to remediate these material weaknesses and performed additional analysis and procedures to conclude that the consolidated financial statements included in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 fairly present, in all material respects, our financial condition and results of operations as of June 30, 2023. However, we may be unable to remediate these weaknesses effectively, and, even if we do remediate these weaknesses, we may in the future identify additional material weaknesses.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a)The following exhibits are filed herewith or incorporated by reference herein:

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
2.1Δ	Agreement and Plan of Merger, dated June 29, 2023, by and among Baudax Bio, Inc., Bounce Merger Sub I, Inc., Bounce Merger Sub II, LLC and TeraImmune, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on July 5, 2023 (File No. 001-39101).

3.1	Second Amended and Restated Bylaws of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023 (File No. 001-39101).
3.2	Certificate of Designations of Series X Non-Voting Convertible Preferred Stock.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 5, 2023 (File No. 001-39101).
4.1	Form of Series A-5 Warrant.	Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed on April 26, 2023 (File No. 333-2771161).
4.2	Form of Series A-6 Warrant.	Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed on April 26, 2023 (File No. 333-2771161).
4.3	Form of Series D Pre-Funded Warrant.	Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on April 26, 2023 (File No. 333-2771161).
4.4	Form of Placement Agent Warrant.	Incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1/A filed on April 26, 2023 (File No. 333-2771161).
10.1	Forbearance Agreement, dated as of June 29, 2023, by and among Baudax Bio, Inc, Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lender party hereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 5, 2023 (File No. 001-39101).
10.1*	Amendment No. 5 and Waiver to Credit Agreement, dated March 29, 2023, by and Baudax Bio, Inc., Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lenders party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 31, 2023 (File No. 001-39101).
10.2	Amendment No. 1 to Forbearance Agreement, dated as of July 30, 2023, by and among Baudax Bio, Inc, Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lender party hereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on July 31, 2023 (File No. 001-39101).
10.3	Form of Securities Purchase Agreement.	Incorporated herein by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-1/A filed on April 26, 2023 (File No. 333-271161).
10.4●	Employment Agreement, by and between Baudax Bio, Inc. and Jillian Dilmore, dated May 10, 2023.	Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023 (File No. 001-39101).
10.5*	Exclusive Patent License Agreement, dated as of June 18, 2020, by and between the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases and TeraImmune, Inc.	Filed herewith.

10.6*	Exclusive License Agreement, dated November 11, 2020, by and between the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and TeraImmune, Inc.	Filed herewith.
10.7*	Exclusive License Agreement, dated August 5, 2019, by and between the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and TeraImmune, Inc.	Filed herewith.
10.8*	Biological Materials License Agreement, dated August 26, 2019, by and between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute and TeraImmune, Inc.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith.

* Certain identified information in the exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.
Δ Schedules have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. Baudax Bio agrees to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that Baudax Bio may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule so furnished.
● Indicates management contract or compensatory plan.

SIGNATURES

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

BAUDAX BIO, INC.

Date: August 16, 2023

By: /s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 16, 2023

By: /s/ Jillian Dilmore
Jillian Dilmore
Corporate Controller
(Principal Financial and Accounting Officer)

Exhibit 10.5

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

L-188-2020

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – EXCLUSIVE

This **Agreement** is based on the model Patent License Exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by
National Institute of Allergy and Infectious Diseases
an Institute or Center (hereinafter referred to as the "**IC**") of the
NIH

and

TeraImmune, Inc.,
hereinafter referred to as the "**Licensee**",
having offices at 704 Quince Orchard Rd., Suite 160, Gaithersburg, MD 20878,
created and operating under the laws of Delaware.

Tax ID No. [***]

For the **IC** internal use only:

License Number:

License Application Number: [***] Serial Number(s) of Licensed Patent(s) or Patent Application(s):

I. U.S. Patent [***], entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [***]

II. U.S. Divisional Application No. [***]- filed October 4, 2016, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells”–claims benefit of 13/716,900. [***]

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): None

Additional Remarks:

Public Benefit(s): T-reg cell therapy for patients with Hemophila A who develop inhibitory anti-FVIII antibodies

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options).

The IC and the Licensee agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the IC investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from IC employees and other inventors, HHS, on behalf of the Government, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. HHS also owns any tangible embodiments of these inventions actually reduced to practice by the IC.

1.3 The Secretary of HHS has delegated to the IC the authority to enter into this Agreement for the licensing of rights to these inventions.

1.4 The IC desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The Licensee desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 “Affiliate(s)” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the Licensee. For this purpose, the term “control” shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 “Benchmarks” mean the performance milestones that are set forth in Appendix D.

2.3 “Biologics License Application (BLA)” means a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2).

2.4 “Commercial Development Plan” means the written commercialization plan attached as Appendix E.

2.5 “CRADA” means a Cooperative Research and Development Agreement.

2.6 “FDA” means the Food and Drug Administration.

2.7 “First Commercial Sale” means the initial transfer by or on behalf of the Licensee or its sublicensees of the Licensed Products or the initial practice of a Licensed Process by or on behalf of the Licensee or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.

2.8 “Government” means the Government of the United States of America.

2.9 “Licensed Fields of Use” means the fields of use identified in Appendix B.

2.10 “Licensed Patent Rights” shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing

from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a):

(i) continuations-in-part of 2.10(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.10(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a): all counterpart foreign and U.S. patent applications and patents to 2.10(a) and 2.10(b), including those listed in Appendix A; and

(d) Licensed Patent Rights shall not include 2.10(b) or 2.10(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.10.(a).

2.11 "Licensed Processes" means processes which, in the course of being practiced, would be within the scope of one or more claims of the Licensed Patent Rights that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.12 "Licensed Products" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the Licensed Patent Rights that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.13 "Licensed Territory" means the geographical area identified in Appendix B.

2.14 "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of the Licensee or its sublicensees, and from leasing, renting, or otherwise making the Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, or sublicensees, and on its payroll, or for the cost of collections.

2.15 "Orphan Indication" means a disease that affects less than two hundred thousand (200,000) people in the United States as defined by the FDA or five (5) in ten thousand (10,000) people in the European Union as defined by the European Medicines Agency.

2.16 "Orphan Drug Designation" means the granting of special status by a country and/or government regulatory agency (such as the FDA, European Medicines Agency (EMA), Japanese Ministry of Health, Labour and Welfare (MHLW), or Therapeutics Goods Administration (TGA) to a drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor under the U.S. Orphan Drug Act (ODA) or any foreign equivalent(s) to this law enacted by other countries including but not limited to Australia, member countries of European Union, and Japan.

2.17 “Orphan Drug Exclusivity” means exclusive marketing rights granted by a country and/or government regulatory agency (such as the FDA, EMA, MHLW, or TGA) to a drug or biological product (“drug”) to treat a rare and/or neglected disease or condition upon regulatory approval of said drug for a given period of time (which varies from country to country) and which can run concurrently with a patent or not.

2.18 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

2.19 “Research License” means a nontransferable, nonexclusive license to make and to use the Licensed Products or the Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.20 “Priority Review” means, with respect to a human drug application as defined in 21 USC § 379g(l), review and action by the FDA on such application as described in the Manual of Policies and Procedures of the Food and Drug Administration (FDA) and goals identified in the letters described in Section 101(b) of the Prescription Drug User Fee Amendments of 2012.

2.21 “Priority Review Voucher” means a voucher issued by the FDA to the sponsor of a Rare Pediatric Disease Product Application that entitles the holder of such voucher to priority review of a single human drug application submitted under 21 USC § 355(b)(1) or Section 351(a) of the Public Health Service Act [42 USC § 262(a)] after the date of approval of the Rare Pediatric Disease Product Application.

2.22 “Rare Pediatric Disease” means a disease that meets each of the following criteria: (A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; (B) The disease is a rare disease or condition, within the meaning of 21 USC § 360bb.

2.23 “Rare Pediatric Disease Product Application” means a human drug application, as defined in 21 USC § 360ff (a)(4), for a Rare Pediatric Disease.

2.24 “U.S. Orphan Drug Exclusivity” means exclusive marketing rights granted by the FDA upon approval of an orphan drug and can run concurrently with a patent or not. The right prevents the submission or effective approval of Abbreviated New Drug Application (ANDA) or applications (ANDA, 505(b)(2) or “full” New Drug Application (NDA) or BLA) for the same drug for the same orphan disease or condition for seven years after FDA approval.

3. GRANT OF RIGHTS

3.1 The IC hereby grants and the Licensee accepts, subject to the terms and conditions of this Agreement, an exclusive license, and to, under the Licensed Patent Rights and the Orphan Drug Designation in the Licensed Territory to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any Licensed Products in the Licensed Fields of Use and to practice and have practiced any Licensed Process(es) in the Licensed Fields of Use.

3.2 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the IC other than the Licensed Patent Rights regardless of whether these patents are dominant or subordinate to the Licensed Patent Rights.

4. SUBLICENSING

4.1 Upon written approval by IC, which shall include prior review of any sublicense agreement by the IC and which shall not be unreasonably withheld the Licensee may enter into sublicensing agreements under the Licensed Patent Rights and the Orphan Drug Designation.

4.2 The Licensee agrees that any sublicenses granted by it shall provide that the obligations to the IC of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this Agreement shall be binding upon the sublicensee as if it were a party to this Agreement. The Licensee further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the Licensee shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the IC, at the option of the sublicensee, upon termination of this Agreement under Article 13. This conversion is subject to the IC approval and contingent upon acceptance by the sublicensee of the remaining provisions of this Agreement.

4.4 The Licensee agrees to forward to the IC a complete copy of each fully executed sublicense agreement postmarked within [***] days of the execution of the agreement. To the extent permitted by law, the IC agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) the IC reserves on behalf of the Government an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the Licensed Patent Rights throughout the world by or on behalf of the Government and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the Government is a signatory. Prior to the First Commercial Sale, the Licensee agrees to provide the IC with reasonable quantities of the Licensed Products or materials made through the Licensed Processes for IC research use; and

(b) in the event that the Licensed Patent Rights are Subject Inventions made under CRADA, the Licensee grants to the Government, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the Licensed Patent Rights or have the Licensed Patent Rights practiced throughout the world by or on behalf of the Government. In the exercise of this license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the First Commercial Sale, the Licensee agrees to provide the IC with reasonable quantities of the Licensed Products or materials made through the Licensed Processes for IC research use.

5.2 The Licensee agrees that products used or sold in the United States embodying the Licensed Products or produced through use of the Licensed Processes shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the IC.

5.3 The Licensee acknowledges that the IC may enter into future CRADAs under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this Agreement. The Licensee agrees not to unreasonably deny requests for a Research License from future collaborators with the IC when acquiring these rights is necessary in order to make a CRADA project feasible. The Licensee may request an opportunity to join as a party to the proposed CRADA.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the IC reserves the right to grant Research Licenses directly or to require the Licensee to grant Research Licenses on reasonable terms. The purpose of these Research Licenses is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, the IC shall consult with the

Licensee before granting to commercial entities a Research License or providing to them research samples of materials made through the Licensed Processes; and

(b) in exceptional circumstances, and in the event that the Licensed Patent Rights are Subject Inventions made under a CRADA, the Government, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the Licensee to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the Licensed Patent Rights in the Licensed Field of Use on terms that are reasonable under the circumstances, or if the Licensee fails to grant this license, the Government retains the right to grant the license itself. The exercise of these rights by the Government shall only be in exceptional circumstances and only if the Government determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the Licensee;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the Licensee; or

(iii) the Licensee has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) the determination made by the Government under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. ROYALTIES AND REIMBURSEMENT

6.1 The Licensee agrees to pay the IC a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The Licensee agrees to pay the IC a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The Licensee agrees to pay the IC earned royalties as set forth in Appendix C.

6.4 The Licensee agrees to pay the IC benchmark royalties as set forth in Appendix C.

6.5 The Licensee agrees to pay the IC sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this Agreement shall cease to fall within the Licensed Patent Rights for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any Licensed Products or Licensed Processes are covered by more than one of the Licensed Patent Rights.

6.8 On sales of the Licensed Products by the Licensee to sublicensees or on sales made in other than an arm’s-length transaction, the value of the Net Sales attributed under this Article 6 to this transaction shall be

that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights and paid by the IC prior to the effective date of this Agreement, the Licensee shall pay the IC, as an additional royalty, within [***] days of the IC's submission of a statement and request for payment to the Licensee, an amount equivalent to these unreimbursed expenses previously paid by the IC. As of June 1, 2020, said unreimbursed expenses are approximately [***] Dollars ($[***]). In the event that the aforementioned unreimbursed expenses estimate and the actual expenses are different, the Licensee is responsible for full payment of these unreimbursed expenses. Said unreimbursed expenses shall be due and payable according to the following schedule:

[***] U.S. Dollars ($[***]) within [***] days of the date this agreement becomes effective;

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***];

[***] U.S. Dollars ($[***]) within [***] days of [***]: and

The remaining balance of [***] U.S. Dollars ($[***]) within [***]days of [***].

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights and paid by the IC on or after the effective date of this Agreement, the IC, at its sole option, may require the Licensee:

(a) to pay the IC on an annual basis, within [***] days of the IC's submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by the IC to handle these functions. However, in this event, the IC and not the Licensee shall be the client of the law firm; or

(c) in limited circumstances, the Licensee may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the Licensed Patent Rights. In that event, the Licensee shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the IC with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 The IC agrees, upon written request, to provide the Licensee with summaries of patent prosecution invoices for which the IC has requested payment from the Licensee under Paragraphs 6.9 and 6.10. The Licensee agrees that all information provided by the IC related to patent prosecution costs shall be treated as

confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 The Licensee may elect to surrender its rights in any country of the Licensed Territory under any of the Licensed Patent Rights upon [***] days written notice to the IC and owe no payment obligation under Paragraph 6.10 for patent-related expenses paid in that country after [***] days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the IC agrees to take responsibility for, but to consult with, the Licensee in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall furnish copies of relevant patent-related documents to the Licensee.

7.2 Upon the IC's written request, the Licensee shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the IC. In this event, the Licensee shall, subject to the prior approval of the IC, select registered patent attorneys or patent agents to provide these services on behalf of the Licensee and the IC. The IC shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The Licensee and its attorneys or agents shall consult with the IC in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the Licensed Patent Rights and shall provide the IC sufficient opportunity to comment on any document that the Licensee intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, the IC may provide the Licensee with written notice that the IC wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights. If the IC elects to reassume these responsibilities, the Licensee agrees to cooperate fully with the IC, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and to provide the IC with complete copies of any and all documents or other materials that the IC deems necessary to undertake such responsibilities. The Licensee shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the IC's choice.

7.4 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the Licensed Patent Rights and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the Licensed Patent Rights, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 The Licensee agrees to keep accurate and correct records of the Licensed Products made, used, sold, or imported and the Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due the IC. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the IC, by an accountant or other designated auditor selected by the IC for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the IC information relating to the accuracy of reports and royalty payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the Licensee shall reimburse the IC for the cost of the inspection at the time the Licensee pays the unreported

royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within [***] days of the date the IC provides to the Licensee notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this Agreement, the Licensee has provided the IC with the Commercial Development Plan in Appendix E, under which the Licensee intends to bring the subject matter of the Licensed Patent Rights to the point of Practical Application. This Commercial Development Plan is hereby incorporated by reference into this Agreement. Based on this plan, performance Benchmarks are determined as specified in Appendix D.

9.2 The Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within [***] days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture and status of sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The IC also encourages these reports to include information on any of the Licensee's public service activities that relate to the Licensed Patent Rights. If reported progress differs from that projected in the Commercial Development Plan and Benchmarks, the Licensee shall explain the reasons for these differences. In the annual report, the Licensee may propose amendments to the Commercial Development Plan, acceptance of which by the IC may not be denied unreasonably. The Licensee agrees to provide any additional information reasonably required by the IC to evaluate the Licensee's performance under this Agreement. The Licensee may amend the Benchmarks at any time upon written approval by the IC. The IC shall not unreasonably withhold approval of any request of the Licensee to extend the time periods of this schedule if the request is supported by a reasonable showing by the Licensee of diligence in its performance under the Commercial Development Plan and toward bringing the Licensed Products to the point of Practical Application as defined in 37 C.F.R. §404.3(d). The Licensee shall amend the Commercial Development Plan and Benchmarks at the request of the IC to address any Licensed Fields of Use not specifically addressed in the plan originally submitted.

9.3 The Licensee shall report to the IC the dates for achieving Benchmarks specified in Appendix D and the First Commercial Sale in each country in the Licensed Territory within [***] days of such occurrences.

9.4 The Licensee shall submit to the IC, within [***] days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of the Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each royalty report, the Licensee shall submit payment of earned royalties due. If no earned royalties are due to the IC for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the Licensee and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine Net Sales made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the Licensed Product(s) sold in the United States.

9.5 The Licensee agrees to forward semi-annually to the IC a copy of these reports received by the Licensee from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the IC by the Licensee for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in The Wall Street Journal on the day that the payment is due. Any loss of

exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the Licensee. The royalty report required by Paragraph 9.4 shall be mailed to the IC at its address for Agreement Notices indicated on the Signature Page.

9.7 The Licensee shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by the IC on any payment that is more than [***] days overdue at the rate of [***] percent ([***]%) per month. This [***] percent ([***]%) per month rate may be applied retroactively from the original due date until the date of receipt by the IC of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the IC from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by the Licensee shall, to the extent permitted by law, be treated by the IC as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the IC under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The Licensee shall use its reasonable commercial efforts to bring the Licensed Products and the Licensed Processes to Practical Application. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the Commercial Development Plan in Appendix E and performance of the Benchmarks in Appendix D. The efforts of a sublicensee shall be considered the efforts of the Licensee.

10.2 Upon the First Commercial Sale, until the expiration or termination of this Agreement, the Licensee shall use its reasonable commercial efforts to make the Licensed Products and the Licensed Processes reasonably accessible to the United States public.

10.3 The Licensee agrees, after its First Commercial Sale, to make reasonable quantities of the Licensed Products or materials produced through the use of the Licensed Processes available to patient assistance programs.

10.4 The Licensee agrees, after its First Commercial Sale and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the Licensed Products or medical aspects of the prophylactic and therapeutic uses of the Licensed Products.

10.5 The Licensee agrees to supply, to the Mailing Address for Agreement Notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the Licensed Products or the Licensed Processes or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The IC and the Licensee agree to notify each other promptly of each infringement or possible infringement of the Licensed Patent Rights, as well as, any facts which may affect the validity, scope, or enforceability of the Licensed Patent Rights of which either party becomes aware.

11.2 Pursuant to this Agreement and the provisions of 35 U.S.C. Chapter 29, the Licensee may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the Licensed Patent Rights;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the Licensed Patent Rights provided, however, that the IC and appropriate Government authorities shall have the first right to take such actions; and

(d) if the Licensee desires to initiate a suit for patent infringement, the Licensee shall notify the IC in writing. If the IC does not notify the Licensee of its intent to pursue legal action within [***] days, the Licensee shall be free to initiate suit. The IC shall have a continuing right to intervene in the suit. The Licensee shall take no action to compel the Government either to initiate or to join in any suit for patent infringement. The Licensee may request the Government to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the Government be made a party to any suit, the Licensee shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including all costs incurred by the Government in opposing the motion or other action. In all cases, the Licensee agrees to keep the IC reasonably apprised of the status and progress of any litigation. Before the Licensee commences an infringement action, the Licensee shall notify the IC and give careful consideration to the views of the IC and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patent Rights shall be brought against the Licensee or raised by way of counterclaim or affirmative defense in an infringement suit brought by the Licensee under Paragraph 11.2, pursuant to this Agreement and the provisions of 35 U.S.C. Chapter 29 or other statutes, the Licensee may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the Licensed Patent Rights;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the Licensed Patent Rights-provided, however, that the IC and appropriate Government authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) if the IC does not notify the Licensee of its intent to respond to the legal action within a reasonable time, the Licensee shall be free to do so. The Licensee shall take no action to compel the Government either to initiate or to join in any declaratory judgment action. The Licensee may request the Government to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the Government be made a party to any suit by motion or any other action of the Licensee, the Licensee shall reimburse the Government for any costs, expenses, or fees, which the Government incurs as a result of the motion or other action. If the Licensee elects not to defend against the declaratory judgment action, the IC, at its option, may do so at its own expense. In all cases, the Licensee agrees to keep the IC reasonably apprised of the status and progress of any litigation. Before the Licensee commences an infringement action, the Licensee shall notify the IC and give careful consideration to the views of the IC and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements (“Claim Expense”), shall be paid by the Licensee. The value of any recovery made by the

Licensee through court judgment or settlement shall be reduced by the Claim Expense and the adjusted value shall be treated as Net Sales and subject to earned royalties.

11.5 The IC shall cooperate fully with the Licensee in connection with any action under Paragraphs 11.2 or 11.3. The IC agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the Licensee.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The IC offers no warranties other than those specified in Article 1.

12.2 The IC does not warrant the validity of the Licensed Patent Rights and makes no representations whatsoever with regard to the scope of the Licensed Patent Rights, or that the Licensed Patent Rights may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE IC MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The IC does not represent that it shall commence legal actions against third parties infringing the Licensed Patent Rights.

12.5 The Licensee shall indemnify and hold the IC, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the Licensee, its sublicensees, directors, employees, or third parties of any Licensed Patent Rights; or

(b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or materials by the Licensee, or other products or processes developed in connection with or arising out of the Licensed Patent Rights.

12.6 The Licensee agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the Licensed Patent Rights, or U.S. Orphan Drug Exclusivity unless sooner terminated as provided in this Article 13.

13.2 In the event that the Licensee is in default in the performance of any material obligations under this Agreement, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within [***] days after the date of notice in writing of the default, the IC may terminate this Agreement by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the Licensee becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party’s intention to file an involuntary petition in bankruptcy, the Licensee shall immediately notify the IC in writing.

13.4 The Licensee shall have a unilateral right to terminate this Agreement or any licenses in any country or territory by giving the IC [***] days written notice to that effect.

13.5 The IC shall specifically have the right to terminate or modify, at its option, this Agreement, if the IC determines that the Licensee:

(a) is not executing the Commercial Development Plan submitted with its request for a license and the Licensee cannot otherwise demonstrate to the IC's satisfaction that the Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve the Practical Application of the Licensed Products or the Licensed Processes;

(b) has not achieved the Benchmarks as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this Agreement;

(d) has committed a material breach of a covenant or agreement contained in this Agreement;

(e) is not keeping the Licensed Products or the Licensed Processes reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the IC shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the Licensee under Paragraph 9.2. Prior to invoking termination or modification of this Agreement under Paragraph 13.5, the IC shall give written notice to the Licensee providing the Licensee specific notice of, and a ninety (90) day opportunity to respond to, the IC's concerns as to the items referenced in 13.5(a)-13.5(g). If the Licensee fails to alleviate the IC's concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the IC's satisfaction, the IC may terminate this Agreement.

13.7 When the public health and safety so require, and after written notice to the Licensee providing the Licensee a [***] day opportunity to respond, the IC shall have the right to require the Licensee to grant sublicenses to responsible applicants, on reasonable terms, in any Licensed Fields of Use under the Licensed Patent Rights, unless the Licensee can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the Licensed Patent Rights. The IC shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the Licensee.

13.8 The IC reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this Agreement if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the Licensee.

13.9 Within [***] days of receipt of written notice of the IC's unilateral decision to modify or terminate this Agreement, the Licensee may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated IC official or designee. The decision of the designated IC official or

designee shall be the final agency decision. The Licensee may thereafter exercise any and all administrative or judicial remedies that may be accessible.

13.10 Within [***] days of expiration or termination of this Agreement under this Article 13, a final report shall be submitted by the Licensee. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the IC shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the IC pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this Agreement, upon termination or expiration of this Agreement, the Licensee shall return all Licensed Products or other materials included within the Licensed Patent Rights to the IC or provide the IC with certification of the destruction thereof. The Licensee may not be granted additional IC licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of the Government to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by the Government or excuse a similar subsequent failure to perform any of these terms or conditions by the Licensee.

14.2 This Agreement constitutes the entire agreement between the parties relating to the subject matter of the Licensed Patent Rights, the Licensed Products and the Licensed Processes, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this Agreement.

14.3 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

14.4 If either party desires a modification to this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this Agreement or their designees.

14.5 The construction, validity, performance, and effect of this Agreement shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This Agreement shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the Licensee’s Affiliate(s) without the prior written consent of the IC. The parties agree that the identity of the parties is material to the formation of this Agreement and that the obligations under this Agreement are nondelegable. In the event that the IC approves a proposed assignment,

the Licensee shall pay the IC, as an additional royalty, [***] percent ([***]%) of the fair market value of any consideration received for any assignment of this Agreement within [***] days of the assignment.

14.8 The Licensee agrees in its use of any IC-supplied materials to comply with all applicable statutes, regulations, and guidelines, including NIH and HHS regulations and guidelines. The Licensee agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The Licensee agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the IC, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the IC of research involving human subjects or clinical trials outside of the United States shall be given no later than [***] days prior to commencement of the research or trials.

14.9 The Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. Government or written assurances by the Licensee that it shall not export these items to certain foreign countries without prior approval of this agency. The IC neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The Licensee agrees to mark the Licensed Products or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the Licensed Products manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the IC's patent rights in those countries.

14.11 By entering into this Agreement, the IC does not directly or indirectly endorse any product or service provided, or to be provided, by the Licensee whether directly or indirectly related to this Agreement. The Licensee shall not state or imply that this Agreement is an endorsement by the Government, the IC, any other Government organizational unit, or any Government employee. Additionally, the Licensee shall not use the names of the IC, the FDA or the HHS or the Government or their employees in any advertising, promotional, or sales literature without the prior written approval of the IC.

14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this Agreement or a breach of this Agreement, except for appeals of modifications or termination decisions provided for in Article 13. The Licensee agrees first to appeal any unsettled claims or controversies to the designated IC official, or designee, whose decision shall be considered the final agency decision. Thereafter, the Licensee may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this Agreement required by the laws of any Licensed Territory as a prerequisite to enforceability of the Agreement in the courts of any foreign jurisdiction or for other reasons shall be carried out by the Licensee at its expense, and appropriately verified proof of recordation shall be promptly furnished to the IC.

14.15 Paragraphs 4.3, 8.1, 9.5-9.8, 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this Agreement shall survive termination of this Agreement.

14.16 The terms and conditions of this Agreement shall, at the IC's sole option, be considered by the IC to be withdrawn from the Licensee's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Licensee and a fully executed original is received by the IC within [***]days from the date of the IC's signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – EXCLUSIVE

SIGNATURE PAGE

For the IC:

/s/ Micheal R. Mowatt 06/18/2020
Micheal R. Mowatt Date
Director
Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

[***]

For the Licensee (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Licensee made or referred to in this document are truthful and accurate.):

by:
/s/ Yong Chan Kim 06/18/2020
Signature of Authorized Official

Yong Chan Kim
Printed Name

Chief Executive Officer
Title

I. Official and Mailing Address for Agreement notices:

Jihoon Park
Chief Operation Officer
Mailing Address:
TeraImmune, Inc.
704 Quince Orchard Rd., Suite 160, Gaithersburg, MD 20878

Email Address: [***]
Phone: 301-646-8683
Fax: 240-306-1200

II. Official and Mailing Address for Financial notices (the Licensee's contact person for royalty payments)

Jihoon Park
Name
Chief Operating Officer
Title

Mailing Address:
TeraImmune, Inc.
704 Quince Orchard Rd., Suite 160
Gaithersburg, MD 20878

Email Address: [***]
Phone: 301-646-8683
Fax: 240-306-1200

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I. U.S. Patent [***], entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [***]

II. U.S. Divisional Application No. [***]- filed October 4, 2016, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells”–claims benefit of 13/716,900. [***]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. Licensed Fields of Use:

Human cell-based therapeutics for the treatment of Hemophilia A in patients that have inhibitory Factor VIII antibodies.

II. Licensed Territory: U.S.

APPENDIX C – ROYALTIES

Royalties:

I. The Licensee agrees to pay to the IC a noncreditable, nonrefundable license issue royalty in the amount of [***]dollars ($[***]) within [***]days from the effective date of this Agreement.

II. The Licensee agrees to pay to the IC a nonrefundable minimum annual royalty of [***]dollars ($[***]) due within [***]days of the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1; and Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year:

(i) [***] U.S. dollars ($[***]) for years [***]through [***].

(ii) [***]U.S. dollars ($[***]) for years [***]through [***].

(iii) [***]U.S. dollars ($[***]) starting January 1 of the year following the First Commercial Sale until expiration of this Agreement as provided for in paragraph 13.1 of this Agreement.

III. The Licensee agrees to pay the IC earned royalties of [***] percent ([***]%) on Net Sales by or on behalf of the Licensee and its sublicensees. Upon expiration of the Licensed Patent Rights, Licensee agrees to pay IC earned royalties of [***]percent ([***]%) on Net Sales by or on behalf of Licensee and its sublicensees for the duration of U.S. Orphan Drug Exclusivity period.

IV. The Licensee agrees to pay the IC Benchmark royalties within [***] ([***]) days of achieving each Benchmark:

(a) [***] U.S. dollars ($[***]) after [***]

(b) [***] U.S. dollars ($[***]) after [***]

(c) [***] thousand U.S. dollars ($[***] after [***]

(d) [***] thousand U.S. dollars ($[***]) after [***]

(e) [***] thousand U.S. dollars ($[***]) upon [***]

V. The Licensee agrees to pay the IC additional sublicensing royalties of [***] percent ([***]%) up to the completion of Phase I clinical trials and [***] percent ([***]%) thereafter on the fair market value of any consideration received for granting each sublicense within [***] ([***]) days of the execution of each sublicense.

VI. If a Priority Review Voucher is granted to the Licensee by the FDA, and the Licensee transfers or sells the Priority Review Voucher to a third party, then the following royalty tiers shall apply:

(a) If the value of the sale is below [***] dollars ($[***]), the value of the royalty shall be [***] percent ([***]%) of the Net Sale price to such third party;

(a) If the value of the sale is between [***] dollars ($[***]) and [***] dollars ($[***]), the value of the royalty shall be [***] percent ([***]%) of the Net Sale price to such third party; and

(b) If the value of the sale is above [***] dollars ($[***]), the value of the royalty shall be [***] percent ([***]%) of the Net Sale price to such third party.

APPENDIX D – BENCHMARKS AND PERFORMANCE

The Licensee agrees to the following Benchmarks for its performance under this Agreement and, within [***] ([***]) days of achieving a Benchmark, shall notify the IC that the Benchmark has been achieved.

I. [***]

II. [***]

III. [***]

IV. [***]

V. [***]

VI. [***]

Exhibit 10.6

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

EXCLUSIVE LICENSE AGREEMENT

BETWEEN

THE HENRY M. JACKSON FOUNDATION FOR THE
ADVANCEMENT OF MILITARY MEDICINE, INC.

AND

TERAIMMUNE, INC.

THIS EXCLUSIVE LICENSE AGREEMENT is entered into as of the date of the last signature on the signature page of this document (the "Effective Date"), by and between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a tax-exempt corporation organized under the laws of the State of Maryland and having its principal offices at 6720A Rockledge Drive, Suite 100, Bethesda, Maryland 20817 ("HJF") and TeraImmune, Inc., a corporation organized under the laws of Delaware and having its principal offices 704 Quince Orchard Rd, Ste 160, Gaithersburg, MD 20878 ("TeraImmune" or "Licensee"). HJF and Licensee sometimes are referred to collectively herein as the "Parties" or individually as a "Party."

WHEREAS, HJF and the Uniformed Services University of the Health Sciences, an institution of higher learning within the Department of Defense, an agency of the United States Government, located at 4301 Jones Bridge Road, Bethesda, Maryland 20814 ("USU"), have agreed to collaborate in the development and commercialization of inventions, patents and other intellectual property rights;

WHEREAS, HJF and USU are committed to the policy that ideas or creative works produced at HJF and USU should be used for the greatest possible public benefit and that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest;

WHEREAS, HJF, by assignment from inventor, Dr. Yong Chan Kim, is an owner of certain Patent Rights (as hereinafter defined) and has the right to grant licenses of said Patent Rights, subject only to a royalty-free, nonexclusive license heretofore granted to or retained by the United States Government;

WHEREAS, HJF inventor Dr. Yong Chan Kim is no longer employed by HJF;

WHEREAS, Licensee shall commit itself to a program of exploiting the Patent Rights (as hereinafter defined) so that public utilization shall result therefrom; and WHEREAS, Licensee desires to obtain from HJF, and HJF agrees to grant to Licensee, a license upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth in this Agreement, the Parties, intending to be legally bound, agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

1.1 “Affiliate” means, with respect to any Person, any other Person that directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Person. For purposes of this definition, the term “controls” (including its correlative meanings “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

1.2 “Agreement” means this Agreement, including all Appendices hereto, as the same may be amended from time to time in accordance with the terms hereof.

1.3 “Business Day” means any day other than a Saturday, a Sunday, or a day on which banking institutions in New York, New York are closed.

1.4 “Confidential Information” means information, disclosed by one Party to the other Party, that is treated as proprietary or confidential by the disclosing Party and, at the time of disclosure, that is marked “proprietary” or “confidential” or that bears a marking or legend of like import restricting its use, copying, or dissemination or that is identified as being confidential in a letter or other written communication sent to the receiving Party prior to or contemporaneously with disclosure to the receiving Party. Any such information that is in another form when disclosed, such as oral or visual, shall be treated as Confidential Information only if and to the extent the disclosing Party informs the receiving Party of the proprietary or confidential nature of the information prior to or at the time of the disclosure, and thereafter creates a written record of the disclosure (marked in accordance with this Agreement) and delivers the written record to the receiving Party promptly, but in no event more than [***] days after the original disclosure to the receiving Party. Confidential Information does not include any information that (i) was known to the receiving Party without a duty of confidentiality before receipt from the disclosing Party as evidenced by written records made prior to such receipt or disclosure (when such prior knowledge did not become known to such receiving Party through disclosure by a third party known to the receiving Party to be subject to an obligation to maintain the confidentiality thereof); (ii) is or becomes a matter of public knowledge through no fault of the receiving Party or any of its agents; (iii) is rightfully received by the receiving Party from a third party without a duty of confidentiality; or (iv) is independently developed by the receiving Party as evidenced by written records of the receiving Party.

1.5 “Field” means all human uses.

1.6 “Licensed Process” means any process that is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights.

1.7 “Licensed Product” means any product or part thereof that: (a) is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights, or (b) is manufactured by using or is employed to practice a Licensed Process.

1.8 “Net Sales” means [***]

1.9 “Non-commercial Research Purposes” means use of Patent Rights for academic research or other not-for-profit scholarly purposes that are undertaken at a non-profit or governmental institution that does not use the Patent Rights in the production or manufacture of products for sale or the performance of services fora fee.

1.10 “Non-royalty Sublicense Income” means any and all sublicense issue fees, sublicense maintenance fees, sublicense milestone payments, and similar non-royalty payments or consideration of any kind (including any non-cash consideration such as debentures, stock, or other debt or equity interests) received by Licensee from sublicensees on account of sublicenses pursuant to this Agreement. Non-royalty Sublicense Income does not include payments made to Licensee for anything other than a sublicense.

1.11 “Patent Rights’’ means any or all of the following intellectual property to the extent owned or controlled by HJF:

(a) the United States and foreign patents and patent application listed in Appendix A and all divisions and continuations of such applications;
(b) United States and foreign patents issued from the application listed in Appendix A or from divisional or continuations of such application;
(c) claims of United States and foreign continuation-in-part applications, and all divisions and continuations of such continuation-in-part applications, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the United States or foreign patent applications listed in Appendix A;
(d) claims of all foreign and United States counterpart patent applications to (a), (b), or (c) above, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the patents or patent applications described in (a), (b), or (c) above; and
(e) any reissues, renewals, extensions, or supplemental protection certificates of patents described in (a), (b), (c), or (d) above.

Patent Rights shall not include (c), (d), or (e) above to the extent that the claims are directed to new matter that is not the subject matter described in (a) above.

1.12 “Person” means any individual, corporation, limited liability company, general or limited partnership, joint venture, association, joint stock company, trust, unincorporated business or organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary, or other capacity.

1.13 “Territory” means worldwide.

1.14 “Valid Claim” means a claim of: (a) any issued, unexpired Patent Right that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal; or (b) any pending application for Patent Right.

ARTICLE II
GRANT OF RIGHTS

2.1 (a) Subject to the terms and conditions hereof, in the Territory and for the Field, HJF hereby grants Licensee an exclusive license (as set forth in Section 2.2 and subject to the restrictions set forth in Section 2.5 below) to practice under the Patent Rights and to research, design, develop, have developed, make, have made, use, have used, sell, have sold, distribute, advertise, exploit, improve and import (and to have another Person do any of the same) Licensed Products and Licensed Processes, until expiration of the last to expire of the Patent Rights, unless this Agreement shall be sooner terminated in accordance with the terms hereof.

(b) Licensee affirms that it intends to pursue development of a product for inducing production of T regulatory cell populations as the first Licensed Product.

2.2 In order to establish a period of commercial exclusivity for Licensee, HJF agrees that it will not grant, for the Field, any other license to develop, have developed, make, have made, use, have used, sell, have sold, export and import Licensed Products or to practice the Licensed Processes, except as required by HJF’s obligations related to Section 2.5(a) or as permitted in Section 2.5(b), for any commercial purpose, during the period of time commencing with the Effective Date and ending with the first to occur of: (a) the termination or expiration of this Agreement in accordance with Article X, or (b) the termination or expiration of the exclusivity of Licensee’s license in accordance with Section 2.5 (b).

2.3 At the end of the exclusive period, the license granted hereunder shall become nonexclusive and shall extend to the end of the last-expiring term for which any of the Patent Rights are granted, unless this Agreement shall be sooner terminated in accordance with the terms hereof.

2.4 During the exclusive period only, and subject to HJF's prior approval, which approval shall not be unreasonably withheld, Licensee shall have the right to grant sublicenses hereunder via written sublicense agreements. Notwithstanding the foregoing, Licensee shall have the right to grant sublicenses hereunder to any Affiliate without the prior approval of HJF.

(a) In all sublicenses granted hereunder, Licensee shall provide that the sublicense is subject and subordinate to all terms and conditions of this Agreement, except: (i) the sublicensee may not grant any sublicenses except with HJF's prior express written approval, and (ii) the rate of royalty on Net Sales paid by the sublicensee to Licensee may exceed the rate set forth in this Agreement. Licensee shall attach a copy of this Agreement to any sublicense agreement (which may be redacted to exclude pricing information) and shall provide a complete copy of the sublicense agreement to HJF promptly after signing by the parties thereto.
(b) Licensee may not receive from any sublicensee anything of value in lieu of cash payments in consideration for any sublicense under this Agreement, without HJF's prior express written approval.
(c) Sublicenses may extend past the expiration date of the exclusive period but any exclusivity of such sublicenses shall expire upon the termination or expiration of Licensee's exclusivity. Upon any termination of this Agreement, sublicensees' rights shall also terminate, subject to Section 10.3 hereof.

2.5 The granting and exercise of this license is subject to the following conditions:
(a) The U.S. Government retains a nonexclusive, nontransferable, irrevocable, world-wide, paid-up license to practice all invention(s) covered by the Patent Rights and to have such invention(s) practiced by or on behalf of the U.S. Government.
(b) HJF and USU reserve the right to:
(i) make and use, and grant to others non-exclusive licenses to make and use for Non-commercial Research Purposes the subject matter described and claimed in Patent Rights; and
(ii) request in writing that Licensee relinquish its exclusive rights hereunder if Licensee has not obtained FDA, or other equivalent, regulatory approval required to sell a Licensed Product within six (6) years after the Effective Date, or achieve any other diligence milestone as set forth in Section IV, which shall be extended, should HJF consent to an extension (which consent shall not be unreasonably withheld) fora reasonable additional period if Licensee is diligently pursuing such approvals in good faith but they have not been issued as of such date. The Parties shall promptly enter into an amendment to this Agreement reflecting Licensee's relinquishment of such license rights.
(iii) request in writing that Licensee return licensed rights to HJF for any given use(s) or indication(s). After such request, Licensee has one-[***] days in which to provide a written response either (A) relinquishing Licensee's rights to some or all of the use(s) or indication(s) requested by HJF; and/or (B) confirming its interest in developing Licensed Products or Licensed Processes for some or all of the use(s) or indication(s) for which HJF is seeking the returned licensed rights; and/or (C) provide a written explanation of how such use(s) or indication(s) would be able to be used to compete with any use(s) or indication(s) developed or being developed by Licensee. For clarity, for each use or indication the return of which has been requested in writing by HJF, Licensee shall satisfy (A), (B), or (C) above. The Parties shall promptly enter into an amendment to this Agreement reflecting any changes to the licensed rights as may be mutually agreed upon.
(c) During the period of exclusivity of this license, Licensee shall cause any Licensed Product produced for use or sale in the United States (including Puerto Rico) to be manufactured substantially in the United States (and/or Puerto Rico).

2.6 The license granted hereunder shall not be construed to confer any rights upon Licensee (or sublicensees, if any) by implication, estoppel, or otherwise as to any technology not included in Patent Rights as defined herein.

ARTICLE III
CONSIDERATION

3.1 Within [***]Business Days of the Effective Date, Licensee shall pay to HJF a non-creditable, non-refundable license issue royalty in the sum of [***] dollars ($[***]).

3.2 Subject to the termination provisions in Article X, Licensee shall pay to HJF semi-annually, within [***]days after each calendar half year ending June 30 and December 31, a royalty on Net Sales by Licensee and sublicensees, according to the following:

a) [***]% royalty on Net Sales worldwide of the licensee and sublicensees if used in combination with previously in-licensed IP as listed in Appendix B.
b) [***]% royalty on worldwide Net Sales of the licensee and sublicensees if technology is used to provide an in-house service such as cell culture.
c) [***]% of annual worldwide Net Sales of kits, or kit components, sold directly by TeraImmune or sublicensee.
d) [***]% of annual worldwide Net Sales of sublicensee for use in its manufacturing process.
e) TeraImmune shall pay to HJF [***] percent ([***]%) of any and all Non-royalty Sublicense Income consideration that TeraImmune receives for sublicenses, other than for royalty or Net Sales, in a form of cash or cash equivalents to the Fair Market Value of shares at the time of the transaction. By way of example, this includes payments from licensing fees, milestone payments or other revenue that TeraImmune receives which is not from a royalty or Net Sale. This consideration shall also include equity investments that include a grant of Patent Rights to a third party and shall not include equity investments that are non-license bearing financial investments in TeraImmune.
f) On sales of Licensed Products or Licensed Processes between Licensee and sublicensees for resale, the royalty shall be paid only on the Net Sales of the sublicensees and not on the Net Sales by Licensee to its sublicensees for resale.

3.3 All payments due hereunder shall be paid in full, without deduction for any taxes or other fees imposed by any government or any transfer, collection, or similar charges; any such tax, fee, or charge shall be paid by Licensee.

3.4 Royalty payments shall be paid by check or by wire transfer in United States dollars in Bethesda, Maryland, or at such other place and manner as HJF may designate in writing to Licensee consistent with the laws and regulations controlling in any foreign country. Royalty payments shall be calculated on Net Sales after Net Sales have been converted to United States Dollars at the actual conversion rate that applied to such conversion or, if such conversion is not made within [***]of Licensee's receipt of such payment, by using the monthly average of the applicable exchange rate existing in the United States as reported in the Wall Street Journal on the last Business Day of the calendar half-year reporting period to which such payments relate.

3.5 No multiple royalty shall be due to HJF because any Licensed Product, its manufacture, use, lease, or sale, is or shall be covered by more than one Patent Rights patent application or Patent Rights patent licensed hereunder.

3.6 In the event that Licensee is legally required to obtain a license from a third party in order to avoid infringing such third party's patent(s) in the development, manufacture, use or sale of any Licensed Product or Licensed Process ("'Third Party License"), then Licensee may reduce the royalty on Net Sales otherwise owed to HJF under Section 3.2 by the amount of such necessary royalties actually paid under the Third Party License on Net Sales of any Licensed Product or Licensed Process, provided that no royalty payment to HJF under this Agreement shall be reduced by more than [***] percent ([***]%). Such deduction shall only apply if Third Party License contains similar royalty stacking provisions so that the royalty rates payable under this Agreement are reduced on a similar or pro rata basis. Licensee shall provide prompt written notice to HJF upon entering into any required Third Party License. For the avoidance of doubt, this Section 3.7 only applies to Third Party Licenses needed to enable use

of the Patent Rights; it does not apply to other licenses or permissions which the Licensee decides to use in developing, producing, marketing or selling finished Licensed Products.

ARTICLE IV
DUE DILIGENCE

4.1 Licensee shall use reasonable best efforts to develop, seek registration and sell Licensed Products derived from the Patent Rights into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment. TeraImmune shall utilize the Patent Rights to [***]within [***] from License Effective Date or all rights granted by HJF shall automatically revert to HJF. In the event Licensee fails to do so, HJF's sole and exclusive remedy for such failure shall be as set forth in Section 2.5(b) (ii). Thereafter, until the expiration of this Agreement, Licensee shall endeavor to keep one or more Licensed Product continuously available to the public for sale in the Territory for the Field.

4.2 Within [***]from the Effective Date, Licensee shall [***].

4.3 Each year, on or before the anniversary of the Effective Date, Licensee shall [***]. Any change [***] that will materially alter or affect the timely achievement of any diligence milestone shall require the consent and approval of HJF, which shall not be unreasonably withheld.

ARTICLE V
REPORTING

5.1 No later than [***] days after December 31 of each calendar year, but only for the first ten years of this Agreement, or until regulatory approval is achieved, Licensee shall provide to HJF a written annual Progress Report summarizing the progress on, research and development, regulatory approvals, manufacturing, sublicensing, marketing, and sales during the most recent twelve (12) month period ending December 31 and Licensee's objectives for the forthcoming year. The Progress Report shall describe the status of Licensee's efforts to develop and commercialize Licensed Product(s) or Licensed Process(es) in reasonable detail to enable HJF to reasonably determine whether anticipated performance and payment milestones have been met and to provide assurance that Licensee is developing Licensed Product(s) or Licensed Process(es). If progress differs from that anticipated in the plan required under Section 4.2, Licensee shall explain the reasons for the difference and propose a modified Commercialization Plan for HJF's review and approval. Licensee shall also provide any reasonable additional data HJF reasonably requires to evaluate Licensee's performance.

5.2 Royalty Reports.

(a) Licensee shall submit to HJF, within [***] days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:

(i) total dollar amount of billings, invoices, and receipts for Licensed Products and Licensed Processes sold by Licensee and all sublicensees worldwide;

(ii) the aggregate deductions applicable to determine the Net Sales;

(iii) a list of each country in which the first sale of the Licensed Products occurred;

(iv) the amount of Non-royalty Sublicense Income received by Licensee; and

(v) the amount of royalty due to HJF for the reporting period or, if no royalties are due for any reporting period, the statement that no royalties are due.

(b) Contemporaneous with submission of each Royalty Report, Licensee shall pay to HJF the amount of royalty due with respect to such half year.

(c) Late payments shall be subject to a charge of [***] percent ([***]%) per month calculated on the amount of the late payment only and not on accrued late payment charges from prior months.

5.3 In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, Licensee shall notify HJF in writing within [***] days of such event.

ARTICLE VI
RECORDKEEPING

6.1 Licensee shall keep, and shall require its sublicensees to keep, accurate records (together with supporting documentation) of Licensed Products and Licensed Processes made, used or sold under this Agreement, appropriate to determine the amount of royalties due to HJF hereunder. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate. No more than once per year, such records shall be available upon reasonable prior notice during normal business hours for examination by an accountant selected by HJF, at its sole cost and expense, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this section, HJF's accountant shall have access to all records directly related to the calculation of royalties under Article III.

6.2 HJF's accountant shall not disclose to HJF any information other than information relating to the accuracy of reports and payments made hereunder. In cases of inaccurate reports and payment, Licensee shall promptly pay HJF any additional sum that would have been payable to HJF had the Licensee reported correctly. Licensee's failure to pay such additional sum within [***] days after a written and substantiated request by HJF shall result in accrual of interest thereafter pursuant to section 5.2(c), provided however that Licensee shall have no obligation to pay such interest rate in the event of a dispute regarding the accountant's findings.

6.3 Such examination by HJF's accountant shall be at HJF's expense, except that if such examination shows an underreporting or underpayment in excess of [***]percent ([***]%) for any twelve (12) month period, then Licensee shall pay HJF the cost of such examination (as well as any additional sum that would have been payable to HJF had the Licensee reported correctly. Licensee's failure to pay such additional sum within [***] days after written request by HJF shall result in accrual of interest thereafter pursuant to section 5.2(c), provided however that Licensee shall have no obligation to pay such interest rate in the event of a dispute regarding the accountant's findings.

ARTICLE VII
DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

7.1 Licensee Prosecution of Patent Applications and Maintenance of Patents.

(a) As of the Effective Date, Licensee shall be responsible for the preparation, filing, prosecution, and maintenance of the Patent Rights and payment of all expenses related thereto. HJF has no obligation to pay for any expense related to the Patent Rights.(b) Licensee shall consult with HJF as to the preparation, filing, prosecution and maintenance of the licensed Patent Rights and agrees to keep HJF promptly and fully informed of the course of patent prosecution of the licensed Patent Rights, by providing the HJF with copies of all documents relevant to any such preparation, filing, prosecution, or maintenance, including but not limited to substantive communications and notices, search reports, third party observations submitted to or received from patent offices throughout the Territory, foreign patent applications, office actions and examination reports from patent offices, and proposed draft responses. HJF shall have the right to review all such documents, prior to their submission, and may offer recommendations to Licensee to amend such contemplated preparation, filing, prosecution, or maintenance, and provide a list of the countries where the HJF desires Licensee to file patent applications. Licensee will make reasonable efforts to implement such HJF recommendations, provided the HJF recommendations are acceptable to outside patent counsel and are received in sufficient time to meet any pertinent deadlines.

(b) In the event the Licensee elects not to, or fails to, continue prosecution or maintenance, in whole or in part, of any licensed Patent Rights in any particular country or countries, HJF shall have the right (but not the obligation) at its own expense to undertake the prosecution and maintenance of the licensed Patent Rights in such countries and Licensee will cooperate fully with HJF, including executing all papers and instruments or requiring employees or agents to execute such papers and instruments so as to enable HJF to prosecute and maintain the Patent Rights in such countries. The Licensee shall notify HJF in writing of any election not to

pursue the prosecution or maintenance of licensed Patent Rights within the Patent Rights at least [***] days prior to any applicable deadline or loss of rights.

7.2 HJF and Licensee shall cooperate fully in the prosecution and maintenance of Patent Rights licensed to Licensee hereunder, executing all papers and instruments or requiring employees or agents to execute such papers and instruments so as to enable Licensee to apply for, to prosecute, and to maintain patent applications and patents in any country. Each Party shall provide to the other prompt notice as to all matters that come to its attention and that may affect the preparation, filing, prosecution, or maintenance of any such patent applications or patents.

7.3 Licensee may elect to surrender its Patent Rights in any country upon [***] days written notice to HJF. Such notice shall not relieve Licensee from responsibility to pay for patent-related expenses incurred prior to the expiration of the [***] day notice period (or such longer period specified in Licensee's notice).

ARTICLE VIII
INFRINGEMENT

8.1 (a) With respect to any Patent Rights that are exclusively licensed to Licensee pursuant to this Agreement, Licensee shall have the right but not the obligation, within the Field and Territory, to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action. HJF agrees to notify Licensee promptly of each infringement of such patents of which HJF is or becomes aware. Before Licensee commences an action with respect to any infringement of such patents, Licensee shall give consideration to the views of HJF in making its decision whether or not to sue.

(b) If Licensee elects to commence an action as described above, HJF may, to the extent permitted by law, elect to join as a party in that action at its sole cost and expense. Regardless of whether HJF elects to join as a party, HJF shall cooperate fully with Licensee in connection with any such action.

8.2 If Licensee elects to commence an action as described above, Licensee may deduct from its royalty payments to HJF with respect to the patent(s) subject to suit an amount not exceeding [***] percent ([***]%) of Licensee's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed [***] percent ([***]%) of the total royalty due to HJF with respect to the patent(s) subject to suit for each calendar year. If such [***] percent ([***]%) of Licensee's expenses and costs exceeds the amount of royalties paid by Licensee for any calendar year, Licensee may to that extent reduce the royalties due to HJF from Licensee in succeeding calendar years, but never by more than [***] percent ([***]%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

8.3 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HJF, which consent shall not be unreasonably withheld or delayed.

8.4 Recoveries or reimbursements from actions commenced pursuant to this Article shall be applied to first reimburse Licensee and then HJF for litigation costs not paid from royalties and then to reimburse HJF for royalties deducted by Licensee pursuant to Section 8.2. Licensee shall receive [***] percent ([***]%) of the remaining recoveries and HJF shall receive [***] percent ([***]%) of the remaining recoveries.

8.5 If Licensee elects not to exercise its right to prosecute an infringement of the Patent Rights pursuant to this Article, HJF may do so at its own expense, controlling such action and retaining all recoveries therefrom. Licensee shall cooperate fully with HJF in connection with any such action.

8.6 Without limiting the generality of Section 8.5, HJF may, at its election and by notice to Licensee, establish a time limit of [***] days for Licensee to decide whether to prosecute any infringement of which HJF is or becomes aware. If, by the end of such [***] day period, Licensee has not commenced such an action, HJF may prosecute such an infringement at its own expense, controlling such action and retaining [***] percent ([***]%) of all recoveries therefrom while Licensee shall receive [***]percent ([***]%) of the recoveries. With respect to any such

infringement action prosecuted by HJF in good faith, Licensee shall pay over to HJF any payments (whether or not designated as "royalties") made by the alleged infringer to Licensee under any existing or future sublicense authorizing Licensed Products or Licensed Processes, up to the amount of HJF's litigation expenses (including, but not limited to, reasonable attorneys' fees).

8.7 If a declaratory judgment action is brought naming Licensee as a defendant and alleging invalidity of any of the Patent Rights, HJF has the right but not the obligation to take over the sole defense of the action at its own expense. Licensee is required to notify HJF of any Licensee decision not to defend such action within [***] days of it being served. Licensee and HJF shall cooperate fully in connection with any such action.

8.8 During the exclusive period of the Licensee's license hereunder, Licensee shall have the sole right, in accordance with the terms and conditions hereof, to sublicense any alleged infringer within the Territory for the Field. Any upfront fees shall be shared equally between Licensee and HJF; other royalties paid in connection with such sublicense shall be treated in accordance with Article III.

ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1 HJF represents and warrants that to HJF's knowledge HJF is the owner of the Patent Rights (subject to the restrictions set forth in Sections 2.2 and 2.5 above) and has the right to grant licenses, and that HJF has the full power and authority to enter into this Agreement and to perform HJF's obligations required under this Agreement.

9.2 HJF represents and warrants that it will not knowingly grant any rights to the Patent Rights to any third party that are inconsistent with the rights granted to Licensee herein.

9.3 EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE IX, HJF MAKES NO AND EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, IMPLIED AND EXPRESS, INCLUDING THOSE CONCERNING THE VALIDITY, ENFORCEABILITY AND SCOPE OF THE LICENSED PATENT RIGHTS, THE ACCURACY, COMPLETENESS, SAFETY, USEFULNESS, LIKELIHOOD OF SUCCESS, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE PATENT RIGHTS OR INFORMATION SUPPLIED BY HJF, OR OF THE LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT. HJF MAKES NO REPRESENTATIONS WHATSOEVER THAT THE PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE OR ANY SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS.

9.4 Licensee represents and warrants that Licensee has not previously entered into and will not enter into any agreement with an unrelated third Person that is inconsistent with the obligations of Licensee herein, and that Licensee has full power, right and authority to enter into and carry out its obligations under this Agreement.

9.5 Licensee represents and warrants that it has not received any notice or threat of any claim, suit, action, or proceeding, and has no knowledge or reason to know of any information, that could: (a) invalidate or render unenforceable any claim of the Patent Rights; or (b) cause any claim of the Patent Rights to fail to issue or be materially limited or restricted as compared with its currently pending scope.

9.6 Each Party warrants and represents to the other Party as follows as of the Effective Date and on a continuing basis throughout the term of this Agreement that:

(a) Organization - such Party is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its incorporation;
(b) Enforceability - this Agreement constitutes the lawful, valid, and legally binding obligation of such Party, enforceable in accordance with its terms;

ARTICLE X
TERMINATION OF AGREEMENT

10.1 This Agreement, unless terminated as provided herein, shall remain in effect until the full end of the term or terms of all the Patent Rights on a country-by-country basis.

10.2 HJF may terminate this Agreement only in the circumstances set forth in this Section and Section 11.3(e), and any such termination shall be effective immediately upon HJF giving written notice to Licensee of any of the following unless a different time frame is specified in this Section:

(a) if Licensee does not meet any of the diligence milestone events in Section 4;
(b) if Licensee does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 5.2(c)) within [***] days after Licensee's receipt of notice in writing of such non-payment;
(c) if Licensee defaults in its obligations under Sections 11.3(d), 11.3(e), and 11.3(f) to procure and maintain insurance and fails to remedy the situation within [***] days of Licensee's receipt of a notice in writing;
(d) if Licensee, or any of its Affiliates or sublicenses, challenges, whether as a claim, cross-claim, counterclaim, or defense, the validity or enforceability of any of the licensed Patent Rights before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction;
(e) if Licensee; is unable to pay its debts as such debts become due; makes a general assignment for the benefit of creditors; has a petition in bankruptcy or a suit seeking reorganization, liquidation, dissolution, or similar relief filed against it; or files or permits the filing of any petition or answer seeking to adjudicate itself bankrupt or insolvent, or seeking for itself any liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of Licensee or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking or consenting to the appointment of a trustee, custodian, receiver, liquidator or other similar official for Licensee or for any substantial part of its property; or takes any corporate action to authorize any of the foregoing actions;
(f) if Licensee is convicted of a felony relating to the manufacture, use, or sale of any Licensed Product or Licensed Process, or willfully omitted a material fact in the progress report, or any other report required by this Agreement; or
(g) except as provided in Section 4.1 and subsections (a), (b), (c), (d), (e) or (f) above, if Licensee defaults in the performance of any material obligations under this Agreement (including Licensee's obligations under Section 7.2 to use commercially reasonable efforts to pursue issuance of patents) and the default has not been remedied within [***] days after the date of notice in writing of such default by HJF.

10.3 Licensee shall provide, in all sublicenses granted by it under this Agreement, that Licensee's interest in such sublicenses shall at HJF's option terminate or be assigned to HJF upon termination of this Agreement by HJF in accordance with the termination rights set forth above.

10.4 Licensee may terminate this Agreement by giving [***] days advance written notice of termination to HJF, which termination shall become effective as of the end of such [***] period.

10.5 Within [***] days after termination of this Agreement by either Party, Licensee shall submit a final Royalty Report to HJF, and any and all maintenance fees and royalty payments and other fees then due shall become payable. In addition, Licensee shall remain obligated to make, in accordance with the terms of this Agreement, royalty payments on any and all future sales of Licensed Products made but not yet sold at the time of termination, and reimburse HJF for any unreimbursed patent expenses incurred by HJF prior to the receipt of Licensee's termination notice.

10.6 Immediately upon termination pursuant to this Article X, whether by HJF or by Licensee, all licensed Patent Rights shall revert to HJF, and Licensee shall cooperate in good faith in transferring responsibility for all patent prosecution and maintenance to HJF.

10.7 Upon termination, Licensee shall promptly provide to HJF all pre-clinical data and regulatory correspondence derived during development of Licensed Products and Licensed Processes and Licensee shall grant to HJF a non-exclusive, royalty-free license, with the right to sublicense, to manufacture, use and sell improvements, including any and all know-how, to licensed Patent Rights made by Licensee during the period of this Agreement prior to such termination, to the extent that such improvements are dominated by or derived from any of the licensed Patent Rights.

10.8 Articles I and VI and Sections 2.5, 5.2, 7.1, 8.4, 10.5, 10.6, 10.7, 10.8, 11.1 through 11.7 inclusive, 11.9, 11.10, and 11.12 through 11.18 inclusive shall survive any expiration or termination of this Agreement indefinitely. Additionally, any rights or remedies arising out of a breach or violation of any terms of this Agreement will survive any expiration or termination of this Agreement. The expiration or termination of this Agreement shall not discharge either Party from any obligation that it owes to the other Party by reason of any loss, cost, damage, expense, liability, or contractual duty that occurs or arises (or the circumstances, events, or basis of which occurs or arises) prior to such expiration or termination, and shall not affect the right of either Party to institute or maintain any action for damages relating to any breach of this Agreement by the other Party prior to the date of termination. It is the intent of the Parties that any such obligation owed by a Party to the other Party arising before the date of expiration or termination (whether the same shall be known or unknown at such date, or whether the circumstances, events, or basis of the same shall be known or unknown at such date), including royalty obligations (computed in accordance with Article III) on sales made or ordered prior to the date of termination or expiration, indemnification obligations, and confidentiality obligations, shall survive the expiration or termination of this Agreement.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Rules of Construction. This Agreement is to be interpreted in accordance with the following rules of construction:

(a) Number and Gender. All definitions of terms apply equally to both the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(b) Including; Herein: Etc. The words “include,” “includes,” and “including” are deemed to be followed by the phrase “without limitation.” The words “herein,” “hereof,” and “hereunder” and words of similar import refer to this Agreement (including all Appendices) in its entirety and are not limited to any part hereof, unless the context shall otherwise require. The word “or” is not exclusive and means “and/or.”

(c) Sales. The terms “sold,” “sell,” and “sale(s)” include leases and other transfers and similar transactions for consideration.

(d) Subdivisions and Attachments. All references in this Agreement to Articles, Sections, subsections, paragraphs, and Appendices are, respectively, references to Articles, Sections, subsections, and paragraphs of, and Appendices to, this Agreement, unless otherwise specified.

(e) References to Documents and Laws. All references to this Agreement or any Appendix hereof are to it as amended, modified, and supplemented from time to time in accordance with the terms of this Agreement. All references to (i) any other agreement or instrument or (ii) any statute, law, regulation, permit, or similar item are to it as amended and supplemented from time to time (and, in the case of a statute, law or regulation, to any corresponding provisions of successor statutes, laws, or regulations), unless otherwise specified.

(f) References to Days. Any reference in this Agreement or Order issued hereunder to a “day” or number of “days” (without the explicit qualification “Business”) is a reference to a calendar day or number of calendar days. If any action or notice is to be taken or given on or by a particular calendar day, and such calendar day is not a Business Day, then such action or notice may be taken or given on the next Business Day.

(g) Examples. If, in any provision of this Agreement any example is given (through the use of the words "such as," "for example," "e.g." or otherwise) of the meaning, intent, or operation of any provision of this Agreement, such example is intended to be illustrative only and not exclusive.
(h) Currency. Except as expressly provided herein, all prices or other monetary amounts stated in this Agreement are, and all monetary amounts stated in any report to be delivered pursuant hereto shall be, stated in United States Dollars.
(i) Participation in Drafting. Both Parties and their respective legal counsel have participated, or had the opportunity to participate, in the drafting of this Agreement, and this Agreement will be construed simply and according to its fair meaning and not strictly for or against either Party.

11.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER THE PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. HJF'S AGGREGATE LIABILITY FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY LICENSEE TO HJF UNDER THIS AGREEMENT. The foregoing exclusions and limitations shall apply to all claims and actions of any kind, whether based on contract, tort (including but not limited to negligence), or any other grounds except that such exclusions and limitations shall not apply to Licensee's indemnification obligations under Section 11.3.

11.3 Indemnification and Insurance.
(a) Licensee shall indemnify, defend and hold harmless HJF and its current and former directors, board members, trustees, officers, employees, and agents and their respective successors, heirs and assigns (collectively, the "Indemnitees"), from and against any and all third party claims, liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation) (collectively "Claims") based upon, arising out of, or otherwise relating to Claims that arise out of or are related to (i) Licensee's manufacture and sale of Licensed Product, (ii) the failure of Licensee to comply with all laws, rules and/or regulations of any jurisdiction applicable to this Agreement; or (iii) the breach of any representation or warranty by Licensee in this Agreement. HJF will promptly notify Licensee within a reasonable time after it becomes aware of any Claim that may be subject to indemnification pursuant to this Section and will cooperate with and authorize Licensee to carry out the sole management and defense of such Claim. In the event HJF decides to employ its own separate counsel in connection with the sole management and defense by Licensee of the Claim, the employ of such counsel shall be at HJF's sole expense. HJF will not compromise or settle any claim, action or proceeding subject to indemnification pursuant to this Section without the prior written approval of Licensee.
(b) HJF shall indemnify, defend and hold harmless the Licensee and its current and former directors, board members, trustees, officers, employees, and agents and their respective successors, heirs and assigns (collectively, the "Licensee Indemnitees"), from and against any and all third party claims, liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation) (collectively "Claims") based upon, arising out of, or otherwise relating to Claims that arise out of or are related to the breach of any representation or warranty by HJF in this Agreement. Licensee will promptly notify HJF within a reasonable time after it becomes aware of any Claim that may be subject to indemnification pursuant to this Section and will cooperate with and authorize HJF to carry out the sole management and defense of such Claim. In the event Licensee decides to employ its own separate counsel in connection with the sole management and defense by HJF of the Claim, the employ of such counsel shall beat Licensee's sole expense. Licensee will not compromise or settle any claim, action or proceeding subject to indemnification pursuant to this Section without the prior written approval of HJF.
(c) The indemnifying Party shall, at its own expense, provide attorneys reasonably acceptable to the other to defend against any actions brought or filed with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

(d) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by any sublicensee or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $[***] per incident and $[***] annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process, or service, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HJF shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions that are in excess of $[***] annual aggregate) such self-insurance program must be acceptable to HJF in its sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limitation of Licensee's liability with respect to its indemnification under this Agreement.
(e) Licensee shall provide HJF with written evidence of such insurance upon request of HJF. Licensee shall provide HJF with written notice at least [***] days prior to the cancellation, non-renewal, or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such [***] day period, HJF shall have the right to terminate this Agreement in accordance with Section 10.2(c).
(f) Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement (i) during the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Licensee or by a sublicensee or agent of Licensee and (ii) a period after the period referred to in (f)(i) above, which period in no event shall be less than [***] years.

11.4 Limitation on Advertising and Publicity. Licensee shall not use HJF's or USU's name or insignia, or the name or insignia of the U.S. Government or any agency thereof, or any adaptation of the foregoing, or the name of any of HJF's or USU's inventors, in any press release, public announcement, advertising, promotional, or sales literature without the prior written approval of HJF or USU, as the case may be.

11.5 No Assignment. Without the prior written approval of HJF in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by Licensee to any person whether voluntarily or involuntarily, by operation of law, or otherwise except that Licensee may assign this Agreement in connection with a sale or transfer of all or substantially all of the relevant business or assets of Licensee without such consent and may assign this Agreement to an Affiliate without such consent. This Agreement shall be binding upon the respective successors, legal representatives, and assignees of HJF and Licensee.

11.6 Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of Maryland, as to all matters, including matters of validity, construction, effect, performance, and remedies, irrespective of any contrary choice of law that otherwise would be applicable under the choice of laws principles of any jurisdiction.

11.7 Compliance with Laws and Regulations. Licensee shall comply with all applicable laws and regulations, including United States laws and regulations controlling exports, if applicable. Licensee agrees that it will be solely responsible for any violation of applicable laws or regulations by Licensee or sublicensees,

11.8 Regulatory Approvals: Patent Markings. Licensee agrees (i) to obtain all regulatory approvals required for the manufacture and sale of Licensed Products and Licensed Processes and (ii) to utilize appropriate patent marking on such Licensed Products. Licensee also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.

11.9 Confidential Information and Intellectual Property. Except as specifically required to comply with obligations set forth in this Agreement, neither Party shall be obligated to disclose or furnish to the other Party any

Confidential Information of such first Party or any confidential or proprietary information, technology, or intellectual property of any third party in such first Party's possession or control. If, however, the Parties have heretofore entered or hereafter enter into a confidential information nondisclosure agreement or similar agreement (the "NDA"), neither Party may terminate the NDA prior to the termination or expiration of this Agreement. If the Parties have not entered into an NDA, each Party agrees, for the greater of a period of five (5) years after each disclosure or during the pendency of this Agreement, to maintain in confidence all Confidential Information disclosed to it by the other Party and to protect such Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the receiving Party uses to protect its own similar confidential information. The obligations of confidentiality and non-use set forth in this Agreement shall not apply with respect to any information that a Party is required to disclose or produce pursuant to applicable law, court order or other valid legal process provided that the disclosing Party promptly notifies the other Party prior to such required disclosure, discloses such information only to the extent so required and cooperates reasonably with the other Party's efforts to contest or limit the scope of such disclosure.

11.10 Headings. The article, section, and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define, or limit the scope, extent, or intent of this Agreement.

11.11 Counterpart Execution. This Agreement and any modification or amendment thereof may be executed in counterparts, both of which shall be considered one and the same agreement, and shall become effective when such counterparts have been signed by each of the Parties and delivered to the other Party.

11.12 Waivers: Remedies Generally. The observance of any term of this Agreement may be waived (whether generally or in a particular instance and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver will be effective only if in a writing signed by the Party against which such waiver is to be asserted. Except as otherwise provided in this Agreement, no failure or delay of either Party in exercising any power, right, or remedy under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any such right, power, or remedy, preclude any other or further exercise thereof or the exercise of any other right, power, or remedy. A waiver by either Party shall be limited to the specific instance in which it is given and, therefore, any waiver by either Party of any obligation of the other Party under or breach by the other Party of this Agreement or of any power, right, or remedy of the waiving Party shall not be a waiver of any other obligation or further or future performance of the same obligation, of any other or succeeding breach, of any other or further exercise of such power, right, or remedy or any other power, right, or remedy.

11.13 Severability. To the extent that any provision of this Agreement shall be judicially unenforceable in any one or more jurisdictions, such provision shall not be affected with respect to any other jurisdiction, each provision with respect to each jurisdiction being construed as several and independent. If any term or provision of this Agreement or the application thereof to any person or circumstance is, to any extent, declared or found to be illegal, unenforceable, or void, then both Parties will be relieved of all obligations arising under such term or provision, but only to the extent that such term or provision is illegal, unenforceable, or void, it being the intent and agreement of the Parties that this Agreement will be deemed amended by modifying such term or provision to the extent necessary to make it legal and enforceable while preserving its intent or, if that is not possible, by substituting therefor another term or provision that is legal and enforceable and achieves the same objective. If the remainder of this Agreement will not be affected by such declaration or finding and is capable of substantial performance, then each term and provision not so affected will be enforced to the extent permitted by law. If necessary to effect the intent of the Parties, the Parties will negotiate in good faith to amend this Agreement to replace the unenforceable language with enforceable language that as closely as possible reflects such intent and to amend any other term or provision thereby rendered incapable of substantial performance or otherwise affected thereby to the extent necessary to permit the practical realization, insofar as legally possible, of the intent of the Parties.

11.14 Relationship of the Parties: Disclaimer of Agency.

(a) Independent Contractors. In entering into and carrying out this Agreement, the Parties will be acting solely as independent contractors. Nothing in this Agreement creates, has created, or will create any

partnership, joint venture, or other business association between the Parties, nor any duties or responsibilities of partners, venturers, or members of a business association.

(b) No Agency. Except for provisions in this Agreement expressly authorizing one Party to act for the other, this Agreement will not constitute either Party as a legal representative or agent of the other Party, nor will either Party have the right or authority to assume, create, or incur any liability or any obligation of any kind, expressed or implied, against or in the name or on behalf of the other Party unless otherwise expressly permitted by such Party.

11.15 No Third Party Beneficiaries. The representations, warranties, covenants, and undertakings contained in this Agreement are for the sole benefit of the Parties, their sublicensees, and the Parties' permitted successors and assigns and shall not be construed as creating any third party beneficiaries of this Agreement or as conferring any rights whatsoever on any third party.

11.16 Notices. Unless otherwise expressly agreed by the Party receiving notice, any notice, demand, or other communication required or permitted to be given by either Party under any provision of this Agreement must be in writing, in the English language, and mailed (certified or registered mail, postage prepaid, return receipt requested) or sent by hand or overnight courier, or by facsimile (with acknowledgment received), charges prepaid and addressed to the intended recipient at such Party's address set forth below, or to such other address or number as such Party may from time to time specify by notice to the other Party as provided in this Section. All notices and other communications given in accordance with the provisions of this Agreement will be deemed to have been given and received (i) when actually delivered by hand, by mail, or by courier, or (ii) when transmitted by facsimile (with acknowledgment received and a copy of such notice is sent no later than the next Business Day by a reliable overnight or two-day courier service, with acknowledgment of receipt).

If to Licensee:

TeraImmune, Inc.
704 Quince Orchard Rd, Ste 160, Gaithersburg, MD 20878

If to HJF:

The Henry M. Jackson Foundation for
the Advancement of Military Medicine, Inc.
ATTN: Chief Technology Officer
6720A Rockledge Drive, Suite 100, Bethesda, MD 20817

11.17 Disputes.

(a) In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the Parties shall try to settle such conflict amicably between themselves. Subject to the exclusions and limitations stated in the final sentence of this Section, any such conflict that the Parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association unless the Parties agree to use an alternate dispute resolution organization, except that only one arbitrator will be selected, and the arbitrator must be in the Washington D.C. Metropolitan Area. In addition, the arbitrator, before being selected, must agree to issue the ruling on the dispute not later than 180 calendar days from the initial filing for arbitration, and shall have no authority to make any award for damages excluded in the agreement, nor for attorneys' fees. Arbitration discovery, to the extent permitted at all, shall be limited. If the Parties do not agree to the scope and nature of discovery, then the arbitrator shall decide the extent to which discovery is allowed. If the arbitrator must decide, then no interrogatories or requests for admission shall be allowed, and depositions, to the extent that any at all are permitted based on a showing of substantial need, shall be limited to no more than three per Party, including no more than one corporate deposition, if allowed. No motions practice will be allowed. Unless the Parties agree, the arbitrator shall decide whether to require pre-hearing exchanges of exhibits and summaries of witness testimony upon which each Party is relying, and proposed rulings and remedies on each issue.

(b) A demand for arbitration or commencement of litigation shall be filed within a reasonable time after the controversy or claim has arisen, and in no event later than the earlier of: (a) six months after the termination or purported termination of this Agreement, or (b) the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitations. For the avoidance of doubt, failure to demand arbitration or commence litigation on an issue arising out of or relating to this Agreement or the breach thereof within the time period set forth in the preceding sentence absolutely precludes the later arbitration or litigation of such issue. Such arbitration shall be held in Montgomery County, Maryland. The award through arbitration shall be final and binding. Either Party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either Party may, without recourse to arbitration, assert against the other Party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant. In addition, notwithstanding the foregoing, disputes over ownership of intellectual property and claims for damages in excess of one million dollars are excluded from arbitration and either Party may commence an action for such disputes in a state court of competent jurisdiction in Montgomery County, Maryland, or, if jurisdiction is proper in federal court, in the appropriate federal District Court for the District of Maryland, and both Parties hereby consent to personal jurisdiction in such state and federal courts in Maryland.

11.18 Entire Agreement; Modifications. This Agreement constitutes the complete agreement between the Parties concerning the subject matter hereof and replaces any prior oral or written communications between the Parties. There are no conditions, understandings, agreements, representations, or warranties, express or implied, that are not specified herein, and neither Party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed by the Parties in writing. Any purported modification or amendment of the express terms or provisions of this Agreement shall be effective only if contained in a written instrument signed by each Party.

SIGNATURES ON THE FOLLOWING PAGE

HJF AND LICENSEE HAVE READ THIS AGREEMENT INCLUDING ALL APPENDICES HERETO AND AGREE TO BE BOUND BY ALL THE TERMS AND CONDITIONS HEREOF AND THEREOF.

IN WITNESS WHEREOF, the Parties have entered into this License Agreement as of the date first above set forth.

THE HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE, INC.

/s/ La Shaun Berrien 11/11/2020
Signature and Date
Name: La Shaun J. Berrien, Ph.D.
Title: Vice President, Research Administration & Innovation Management

TERAIMMUNE, INC.

/s/ Yong Chan Kim 11/11/2020
Signature and Date
Name: Yong Chan Kim
Title: Chief Executive Officer

SCHEDULE A
PATENT RIGHTS

[***]

SCHEDULE B
PREVIOUSLY LICENSED PATENT RIGHTS FROM HJF TO TERAIMMUNE

[***]

Exhibit 10.7

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

EXCLUSIVE LICENSE AGREEMENT

BETWEEN

THE HENRY M. JACKSON FOUNDATION FOR THE

ADVANCEMENT OF MILITARY MEDICINE, INC.

AND

TERAIMMUNE, INC.

THIS EXCLUSIVE LICENSE AGREEMENT is entered into as of the date of the last signature on the signature page of this document (the "Effective Date"), by and between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a tax-exempt corporation organized under the laws of the State of Maryland and having its principal offices at 6720A Rockledge Drive, Suite 100, Bethesda, Maryland 20817 ("HJF") and TeraImmune, Inc., a corporation organized under the laws of Delaware and having its principal offices at 9610 Medical Center Drive, Rockville, Maryland 20852 ("Licensee"). HJF and Licensee sometimes are referred to collectively herein as the "Parties" or individually as a "Party."

WHEREAS, HJF and the Uniformed Services University of the Health Sciences, an institution of higher learning within the Department of Defense, an agency of the United States Government, located at 4301 Jones Bridge Road, Bethesda, Maryland 20814 ("USU"), have agreed to collaborate in the development and commercialization of inventions, patents and other intellectual property rights;

WHEREAS, HJF and USU are committed to the policy that ideas or creative works produced at HJF and USU should be used for the greatest possible public benefit and that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest;

WHEREAS, HJF, by assignment from USU (which received assignment from USU inventor David Scott) and by assignments from HJF inventors Ai-Hong Zhang and Yong Chan Kim, is an owner of certain Patent Rights (as hereinafter defined) and has the right to grant licenses of said Patent Rights, subject only to a royalty-free, nonexclusive license heretofore granted to or retained by the United States Government;

WHEREAS, HJF inventor Yong Chan Kim is no longer employed by HJF and is currently employed by Licensee at its Vice President for Research;

WHEREAS, Licensee shall commit itself to a program of exploiting the Patent Rights (as hereinafter defined) so that public utilization shall result therefrom; and

WHEREAS, Licensee desires to obtain from HJF, and HJF agrees to grant to Licensee, a license upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth in this Agreement, the Parties, intending to be legally bound, agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

1.1 "Affiliate" means, with respect to any Person, any other Person that directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Person. For purposes of this definition, the term "controls" (including its correlative meanings "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

1.2 "Agreement" means this Agreement, including all Appendices hereto, as the same may be amended from time to time in accordance with the terms hereof.

1.3 "Business Day" means any day other than a Saturday, a Sunday, or a day on which banking institutions in New York, New York are closed.

1.4 "Confidential Information" means information, disclosed by one Party to the other Party, that is treated as proprietary or confidential by the disclosing Party and, at the time of disclosure, that is marked "proprietary" or "confidential" or that bears a marking or legend of like import restricting its use, copying, or dissemination or that is identified as being confidential in a letter or other written communication sent to the receiving Party prior to or contemporaneously with disclosure to the receiving Party. Any such information that is in another form when disclosed, such as oral or visual, shall be treated as Confidential Information only if and to the extent the disclosing Party informs the receiving Party of the proprietary or confidential nature of the information prior to or at the time of the disclosure, and thereafter creates a written record of the disclosure (marked in accordance with this Agreement) and delivers the written record to the receiving Party promptly, but in no event more than [***] days after the original disclosure to the receiving Party. Confidential Information does not include any information that (i) was known to the receiving Party without a duty of confidentiality before receipt from the disclosing Party as evidenced by written records made prior to such receipt or disclosure (when such prior knowledge did not become known to such receiving Party through disclosure by a third party known to the receiving Party to be subject to an obligation to maintain the confidentiality thereof); (ii) is or becomes a matter of public knowledge through no fault of the receiving Party or any of its agents; (iii) is rightfully received by the receiving Party from a third party without a duty of confidentiality; or (iv) is independently developed by the receiving Party as evidenced by written records of the receiving Party.

1.5 "Field" means Hemophilia A.

1.6 "Licensed Process" means any process that is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights.

1.7 "Licensed Product" means any product or part thereof that: (a) is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights, or (b) is manufactured by using or is employed to practice a Licensed Process.

1.8 "Net Sales" means [***]

No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by and on the payroll of Licensee or sublicensees, or for the cost of collections.

1.9 "Non-commercial Research Purposes" means use of Patent Rights for academic research or other not-for-profit scholarly purposes that are undertaken at a non profit or governmental institution that does not use the Patent Rights in the production or manufacture of products for sale or the performance of services for a fee.

1.10 “Non-royalty Sublicense Income” means any and all sublicense issue fees, sublicense maintenance fees, sublicense milestone payments, and similar non royalty payments or consideration of any kind (including any non-cash consideration such as debentures, stock, or other debt or equity interests) received by Licensee from sublicensees on account of sublicenses pursuant to this Agreement. Non-royalty Sublicense Income does not include payments made to Licensee for anything other than a sublicense.

1.11 “Patent Rights” means any or all of the following intellectual property to the extent owned or controlled by HJF:

(a) the United States and foreign patents and patent applications listed in Appendix A and all divisions and continuations of such applications;

(b) United States and foreign patents issued from the applications listed in Appendix A or from divisionals or continuations of such applications;

(c) claims of United States and foreign continuation-in-part applications, and all divisions and continuations of such continuation-in-part applications, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the United States or foreign patent applications listed in Appendix A;

(d) claims of all foreign and United States counterpart patent applications to (a), (b), or (c) above, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the patents or patent applications described in (a), (b), or (c) above; and

(e) any reissues, renewals, extensions, or supplementary protection certificates of patents described in (a), (b), (c), or (d) above.

Patent Rights shall not include (c), (d), or (e) above to the extent that the claims are directed to new matter that is not the subject matter described in (a) above.

1.12 “Person” means any individual, corporation, limited liability company, general or limited partnership, joint venture, association, joint stock company, trust, unincorporated business or organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary, or other capacity.

1.13 “Territory” means worldwide.

1.14 “Valid Claim” means a claim of: (a) any issued, unexpired Patent Right that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal; or (b) any pending application for Patent Right.

ARTICLE II
GRANT OF RIGHTS

2.1 (a) Subject to the terms and conditions hereof, in the Territory and for the Field, HJF hereby grants Licensee an exclusive license (as set forth in Section 2.2 and subject to the restrictions set forth in Section 2.5 below) to practice under the Patent Rights and to research, design, develop, have developed, make, have made, use, have used, sell, have sold, distribute, advertise, exploit, improve and import (and to have another Person do any of the same) Licensed Products and Licensed Processes, until expiration of the last to expire of the Patent Rights, unless this Agreement shall be sooner terminated in accordance with the terms hereof.

(a) Licensee affirms that it intends to pursue development of a product for treating Hemophilia A as the first Licensed Product.

2.2 In order to establish a period of commercial exclusivity for Licensee, HJF agrees that it will not grant, for the Field, any other license to develop, have developed, make, have made, use, have used, sell, have sold, export and import Licensed Products or to practice the Licensed Processes, except as required by HJF's obligations related to Section 2.5(a) or as permitted in Section 2.5(b), for any commercial purpose, during the period of time commencing with the Effective Date and ending with the first to occur of: (a) the termination or expiration of this Agreement in accordance with Article X, or (b) the termination or expiration of the exclusivity of Licensee's license in accordance with Section 2.5 (b).

2.3 At the end of the exclusive period, the license granted hereunder shall become nonexclusive and shall extend to the end of the last-expiring term for which any of the Patent Rights are granted, unless this Agreement shall be sooner terminated in accordance with the terms hereof.

2.4 During the exclusive period only, and subject to HJF's prior approval, which approval shall not be unreasonably withheld, Licensee shall have the right to grant sublicenses hereunder via written sublicense agreements. Notwithstanding the foregoing, Licensee shall have the right to grant sublicenses hereunder to any Affiliate without the prior approval of HJF.

(a) In all sublicenses granted hereunder, Licensee shall provide that the sublicense is subject and subordinate to all terms and conditions of this Agreement, except: (i) the sublicensee may not grant any sublicenses except with HJF's prior express written approval, and (ii) the rate of royalty on Net Sales paid by the sublicensee to Licensee may exceed the rate set forth in this Agreement. Licensee shall attach a copy of this Agreement to any sub license agreement (which may be redacted to exclude pricing information) and shall provide a complete copy of the sublicense agreement to HJF promptly after signing by the parties thereto.

(b) Licensee may not receive from any sublicensee anything of value in lieu of cash payments in consideration for any sublicense under this Agreement, without HJF's prior express written approval.

(c) Sublicenses may extend past the expiration date of the exclusive period but any exclusivity of such sublicenses shall expire upon the termination or expiration of Licensee's exclusivity. Upon any termination of this Agreement, sublicensees' rights shall also terminate, subject to Section 10.3 hereof.

2.5 The granting and exercise of this license is subject to the following conditions:

(a) The U.S. Government retains a nonexclusive, nontransferable, irrevocable, world-wide, paid-up license to practice all invention(s) covered by the Patent Rights and to have such invention(s) practiced by or on behalf of the U.S. Government.

(b) HJF and USU reserve the right to:

(i) make and use, and grant to others non-exclusive licenses to make and use for Non-commercial Research Purposes the subject matter described and claimed in Patent Rights; and

(ii) request in writing that Licensee relinquish its exclusive rights hereunder if Licensee has not obtained FDA, or other equivalent, regulatory approval required to sell a Licensed Product within [***]years after the Effective Date, or achieve any other diligence milestone as set forth in Appendix B, which shall be extended, should HJF consent to an extension (which consent shall not be unreasonably withheld) for a reasonable additional period if Licensee is diligently pursuing such approvals in good faith but they have not been issued as of such date. The Parties shall promptly enter into an amendment to this Agreement reflecting Licensee's relinquishment of such license rights.

(iii) request in writing that Licensee return licensed rights to HJF for any given use(s) or indication(s). After such request, Licensee has [***]days in which to provide a written response either (A) relinquishing Licensee's

rights to some or all of the use(s) or indication(s) requested by HJF; and/or (B) confirming its interest in developing Licensed Products or Licensed Processes for some or all of the use(s) or indication(s) for which HJF is seeking the returned licensed rights; and/or (C) provide a written explanation of how such use(s) or indication(s) would be able to be used to compete with any use(s) or indication(s) developed or being developed by Licensee. For clarity, for each use or indication the return of which has been requested in writing by HJF, Licensee shall satisfy (A), (B), or (C) above. The Parties shall promptly enter into an amendment to this Agreement reflecting any changes to the licensed rights as may be mutually agreed upon.

(c) During the period of exclusivity of this license, Licensee shall cause any Licensed Product produced for use or sale in the United States (including Puerto Rico) to be manufactured substantially in the United States (and/or Puerto Rico).

2.6 The license granted hereunder shall not be construed to confer any rights upon Licensee (or sublicensees, if any) by implication, estoppel, or otherwise as to any technology not included in Patent Rights as defined herein.

ARTICLE III
ROYALTIES & FEES

3.1 Within [***] ([***]) Business Days of the Effective Date, Licensee shall pay to HJF a non-creditable, non-refundable license issue royalty in the sum of [***] dollars ($[***]).

3.2 Subject to the termination provisions in Article X, Licensee shall pay to HJF semi-annually, within [***] days after each calendar half year ending June 30 and December 31, a royalty on Net Sales by Licensee and sublicensees, according to the following:

a) [***]% of Net Sales in jurisdictions where a Valid Claim exists;

b) [***]% of Net Sales in jurisdictions not covered by any Valid Claim or where previously Valid Claims have expired.

c) In the case of sublicenses, Licensee shall also pay to HJF a royalty of [***]percent ([***]%) of any and all Non-royalty Sublicense Income prior to regulatory approval and [***] percent ([***]%) thereafter.

d) On sales of Licensed Products or Licensed Processes between Licensee and sublicensees for resale, the royalty shall be paid only on the Net Sales of the sublicensees and not on the Net Sales by Licensee to its sublicensees for resale.

3.3 Subject to the termination provisions in Article X, Licensee shall pay to HJF an annual non-refundable license maintenance fee of [***]dollars ($[***]) no later than [***] days after the first anniversary of the Effective Date of this Agreement, [***]dollars ($[***]) no later than [***] days after the second anniversary of the Effective Date of this Agreement, and [***] dollars ($[***]) no later than [***] days after the third anniversary and each anniversary thereafter. The maintenance fee payments shall be credited by Licensee against running royalties due by Licensee to HJF (pursuant to Section 3.2) for the calendar year of the payment only, and Royalty Reports (pursuant to Section 5.3) shall reflect such a credit. Such maintenance fees shall not be credited against any milestone payments nor against royalties due for any other calendar year than the year of payment.

3.4 All payments due hereunder shall be paid in full, without deduction for any taxes or other fees imposed by any government or any transfer, collection, or similar charges; any such tax, fee, or charge shall be paid by Licensee.

3.5 Royalty payments shall be paid by check or by wire transfer in United States dollars in Bethesda, Maryland, or at such other place and manner as HJF may designate in writing to Licensee consistent with the laws and regulations controlling in any foreign country. Royalty payments shall be calculated on Net Sales after Net

Sales have been converted to United States Dollars at the actual conversion rate that applied to such conversion or, if such conversion is not made within [***] days of Licensee's receipt of such payment, by using the monthly average of the applicable exchange rate existing in the United States as reported in the Wall Street Journal on the last Business Day of the calendar half-year reporting period to which such payments relate.

3.6 No multiple royalty shall be due to HJF because any Licensed Product, its manufacture, use, lease, or sale, is or shall be covered by more than one Patent Rights patent application or Patent Rights patent licensed hereunder.

3.7 In the event that Licensee is legally required to obtain a license from a third party in order to avoid infringing such third party's patent(s) in the development, manufacture, use or sale of any Licensed Product or Licensed Process ("Third Party License"), then Licensee may reduce the royalty on Net Sales otherwise owed to HJF under Section 3.2 by the amount of such necessary royalties actually paid under the Third Party License on Net Sales of any Licensed Product or Licensed Process, provided that no royalty payment to HJF under this Agreement shall be reduced by more than [***] ([***]%). Such deduction shall only apply if Third Party License contains similar royalty stacking provisions so that the royalty rates payable under this Agreement are reduced on a similar or pro rata basis. Licensee shall provide prompt written notice to HJF upon entering into any required Third Party License. For the avoidance of doubt, this Section 3.7 only applies to Third Party Licenses needed to enable use of the Patent Rights; it does not apply to other licenses or permissions which the Licensee decides to use in developing, producing, marketing or selling finished Licensed Products.

3.8 Licensee shall pay to HJF the milestone payments as set forth in Appendix B. The milestone payments are not creditable against any other fee, royalty or payment.

ARTICLE IV
DUE DILIGENCE

4.1 Licensee shall timely achieve the diligence milestones set forth in Appendix B including that the Licensee shall bring one or more Licensed Products to market, in the Territory for the Field on or before [***] years from the Effective Date. In the event Licensee fails to do so, HJF's sole and exclusive remedy for such failure shall be as set forth in Section 2.5(b) (ii). Thereafter, until the expiration of this Agreement, Licensee shall endeavor to keep one or more Licensed Product continuously available to the public for sale in the Territory for the Field.

4.2 Within [***] year from the Effective Date, Licensee shall deliver to HJF a commercialization plan ("Commercialization Plan") which sets forth the Licensee's plan for research and development required in order to commercialize Licensed Product(s) and will include (i) development milestones (such as projected dates for FDA filings and entry into clinical trials), (ii) an end-user report which includes the optimum product specifications, and (iii) a strategic plan developed with a regulatory consultant for the purpose of preparing pre-submission regulatory meeting documents.

4.3 Each year, on or before the anniversary of the Effective Date, Licensee shall provide an updated Commercialization Plan to HJF showing any actual or planned changes to previous year's submitted plan. Any change of the Commercialization Plan that will materially alter or affect the timely achievement of any diligence milestone shall require the consent and approval of HJF, which shall not be unreasonably withheld.

ARTICLE V
REPORTING

5.1 No later than [***] days after December 31 of each calendar year, but only for the first ten years of this Agreement, or until regulatory approval is achieved, Licensee shall provide to HJF a written annual Progress Report summarizing the progress on, research and development, regulatory approvals, manufacturing, sublicensing, marketing, and sales during the most recent twelve (12) month period ending December 31 and Licensee's

objectives for the forthcoming year. The Progress Report shall describe the status of Licensee's efforts to develop and commercialize Licensed Product(s) or Licensed Process(es) in reasonable detail to enable HJF to reasonably determine whether anticipated performance and payment milestones have been met and to provide assurance that Licensee is developing Licensed Product(s) or Licensed Process(es). If progress differs from that anticipated in the plan required under Section 4.2, Licensee shall explain the reasons for the difference and propose a modified Commercialization Plan for HJF's review and approval. Licensee shall also provide any reasonable additional data HJF reasonably requires to evaluate Licensee's performance.

5.2 Royalty Reports.

(a) Licensee shall submit to HJF, within [***] days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:

(i) total dollar amount of billings, invoices, and receipts for Licensed Products and Licensed Processes sold by Licensee and all sublicensees worldwide;

(ii) the aggregate deductions applicable to determine the Net Sales;

(iii) a list of each country in which the first sale of the Licensed Products occurred;

(iv) the amount of Non-royalty Sublicense Income received by Licensee; and

(v) the amount of royalty due to HJF for the reporting period or, if no royalties are due for any reporting period, the statement that no royalties are due.

(b) Contemporaneous with submission of each Royalty Report, Licensee shall pay to HJF the amount of royalty due with respect to such half year.

(c) Late payments shall be subject to a charge of [***] percent ([***]%) per month calculated on the amount of the late payment only and not on accrued late payment charges from prior months.

5.3 In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, Licensee shall notify HJF in writing within [***] days of such event.

ARTICLE VI
RECORD KEEPING

6.1 Licensee shall keep, and shall require its sublicensees to keep, accurate records (together with supporting documentation) of Licensed Products and Licensed Processes made, used or sold under this Agreement, appropriate to determine the amount of royalties due to HJF hereunder. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate. No more than once per year, such records shall be available upon reasonable prior notice during normal business hours for examination by an accountant selected by HJF, at its sole cost and expense, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this section, HJF's accountant shall have access to all records directly related to the calculation of royalties under Article III.

6.2 HJF's accountant shall not disclose to HJF any information other than information relating to the accuracy of reports and payments made hereunder. In cases of inaccurate reports and payment, Licensee shall promptly pay HJF any additional sum that would have been payable to HJF had the Licensee reported correctly. Licensee's failure to pay such additional sum within [***] days after a written and substantiated request by HJF shall result in accrual of interest thereafter pursuant to section 5.2(c), provided however that Licensee shall have no obligation to pay such interest rate in the event of a dispute regarding the accountant's findings.

6.3 Such examination by HJF's accountant shall be at HJF's expense, except that if such examination shows an underreporting or underpayment in excess of [***]percent ([***]%) for any twelve (12) month period, then Licensee shall pay HJF the cost of such examination (as well as any additional sum that would have been payable to HJF had the Licensee reported correctly. Licensee's failure to pay such additional sum within [***] days after written request by HJF shall result in accrual of interest thereafter pursuant to section 5.2(c), provided however that Licensee shall have no obligation to pay such interest rate in the event of a dispute regarding the accountant's findings.

ARTICLE VII
DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

7.1 Licensee Prosecution.

(a) Licensee shall be responsible for the preparation, filing, prosecution, maintenance and payment of all expenses related to the licensed Patent Rights. Licensee agrees to prosecute and maintain patent applications listed in Appendix A. Licensee further agrees to file any additional continuation or divisional application(s) required to retain all embodiments of Patent Rights contained in said patent applications, including those embodiments outside the licensed Field. HJF retains the right, in its sole discretion, to be responsible for the preparation, filing, prosecution and maintenance of any continuation or divisional application that claims embodiments of Patent Rights outside of the Field. Licensee agrees not to abandon or otherwise undermine prosecution of embodiments outside the licensed Field.

(b) Licensee shall consult with HJF as to the preparation, filing, prosecution and maintenance of the licensed Patent Rights and agrees to keep HJF promptly and fully informed of the course of patent prosecution of the licensed Patent Rights, by providing the HJF with copies of all documents relevant to any such preparation, filing, prosecution, or maintenance, including but not limited to substantive communications and notices, search reports, third party observations submitted to or received from patent offices throughout the Territory, foreign patent applications, office actions and examination reports from patent offices, and proposed draft responses. HJF shall have the right to review all such documents, prior to their submission, and may offer recommendations to Licensee to amend such contemplated preparation, filing, prosecution, or maintenance, and provide a list of the countries where the HJF desires Licensee to file patent applications. Licensee will make reasonable efforts to implement such HJF recommendations, provided the HJF recommendations are acceptable to outside patent counsel and are received in sufficient time to meet any pertinent deadlines.

(c) In the event the Licensee elects not to, or fails to, continue prosecution, in whole or in part, of any licensed Patent Rights in any particular country or countries, HJF shall have the right (but not the obligation) at its own expense to undertake the prosecution and maintenance of the licensed Patent Rights. The Licensee shall notify HJF in writing of any election not to pursue the prosecution or maintenance of licensed Patent Rights within the Patent Rights at least [***]days prior to any applicable deadline or loss of rights.

(d) HJF shall provide reasonable efforts to aide Licensee in obtaining signatures and/or inventor assistance as necessary to further prosecution and to secure the full protection and ownership of all rights in and to the Licensed Products or Processes.

7.2 Beginning [***]after the Effective Date, Licensee shall pay HJF [***] Dollars ($[***]) per year to reimburse HJF for any expenses related to the preparation, filing, prosecution and maintenance of the Patent Rights prior to the Effective Date ("Pre-License Patent Expenses") until HJF has been reimbursed for all Pre-License Patent Expenses. The Pre-License Patent Expenses are estimated to be [***]dollars ($[***]). Late payment of any such required payment shall be subject to interest charges of [***]percent ([***]%) per month.

7.3 HJF and Licensee shall cooperate fully in the preparation, filing, prosecution and maintenance of Patent Rights and of all patents and patent applications licensed to Licensee hereunder, executing all papers and

instruments or requiring employees or agents to execute such papers and instruments so as to enable HJF or Licensee to apply for, to prosecute, and to maintain patent applications and patents in any country. Each Party shall provide to the other prompt notice as to all matters that come to its attention and that may affect the preparation, filing, prosecution, or maintenance of any such patent applications or patents.

7.4 Licensee may elect to surrender its Patent Rights in any country upon [***]days written notice to HJF. Such notice shall not relieve Licensee from responsibility to reimburse HJF for reasonable Third Party patent-related expenses incurred prior to the expiration of the [***]day notice period (or such longer period specified in Licensee's notice).

ARTICLE VIII
INFRINGEMENT

8.1 (a) With respect to any Patent Rights that are exclusively licensed to Licensee pursuant to this Agreement, Licensee shall have the right but not the obligation, within the Field and Territory, to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action. HJF agrees to notify Licensee promptly of each infringement of such patents of which HJF is or becomes aware. Before Licensee commences an action with respect to any infringement of such patents, Licensee shall give consideration to the views of HJF in making its decision whether or not to sue.

(b) If Licensee elects to commence an action as described above, HJF may, to the extent permitted by law, elect to join as a party in that action at its sole cost and expense.

Regardless of whether HJF elects to join as a party, HJF shall cooperate fully with Licensee in connection with any such action.

8.2 If Licensee elects to commence an action as described above, Licensee may deduct from its royalty payments to HJF with respect to the patent(s) subject to suit an amount not exceeding [***] percent ([***]%) of Licensee's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed [***] percent ([***]%) of the total royalty due to HJF with respect to the patent(s) subject to suit for each calendar year. If such [***] percent ([***]%) of Licensee's expenses and costs exceeds the amount of royalties paid by Licensee for any calendar year, Licensee may to that extent reduce the royalties due to HJF from Licensee in succeeding calendar years, but never by more than [***] percent ([***]%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

8.3 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HJF, which consent shall not be unreasonably withheld or delayed.

8.4 Recoveries or reimbursements from actions commenced pursuant to this Article shall be applied to first reimburse Licensee and then HJF for litigation costs not paid from royalties and then to reimburse HJF for royalties deducted by Licensee pursuant to Section 8.2. Licensee shall receive [***]percent ([***]%) of the remaining recoveries and HJF shall receive [***]percent ([***]%) of the remaining recoveries.

8.5 If Licensee elects not to exercise its right to prosecute an infringement of the Patent Rights pursuant to this Article, HJF may do so at its own expense, controlling such action and retaining all recoveries therefrom. Licensee shall cooperate fully with HJF in connection with any such action.

8.6 Without limiting the generality of Section 8.5, HJF may, at its election and by notice to Licensee, establish a time limit of [***]days for Licensee to decide whether to prosecute any infringement of which HJF is or becomes aware. If, by the end of such [***]day period, Licensee has not commenced such an action, HJF may prosecute such an infringement at its own expense, controlling such action and retaining [***] percent ([***]%) of all recoveries therefrom while Licensee shall receive [***] percent ([***]%) of the recoveries. With respect to any such

infringement action prosecuted by HJF in good faith, Licensee shall pay over to HJF any payments (whether or not designated as "royalties") made by the alleged infringer to Licensee under any existing or future sublicense authorizing Licensed Products or Licensed Processes, up to the amount of HJF's litigation expenses (including, but not limited to, reasonable attorneys' fees).

8.7 If a declaratory judgment action is brought naming Licensee as a defendant and alleging invalidity of any of the Patent Rights, HJF has the right but not the obligation to take over the sole defense of the action at its own expense. Licensee is required to notify HJF of any Licensee decision not to defend such action within [***] days of it being served. Licensee and HJF shall cooperate fully in connection with any such action.

8.8 During the exclusive period of the Licensee's license hereunder, Licensee shall have the sole right, in accordance with the terms and conditions hereof, to sublicense any alleged infringer within the Territory for the Field. Any upfront fees shall be shared equally between Licensee and HJF; other royalties paid in connection with such sublicense shall be treated in accordance with Article III.

ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1 HJF represents and warrants that to HJF's knowledge HJF is the owner of the Patent Rights (subject to the restrictions set forth in Sections 2.2 and 2.5 above) and has the right to grant licenses, and that HJF has the full power and authority to enter into this Agreement and to perform HJF's obligations required under this Agreement.

9.2 HJF represents and warrants that it will not knowingly grant any rights to the Patent Rights to any third party that are inconsistent with the rights granted to Licensee herein.

9.3 EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE IX, HJF MAKES NO AND EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, IMPLIED AND EXPRESS, INCLUDING THOSE CONCERNING THE VALIDITY, ENFORCEABILITY AND SCOPE OF THE LICENSED PATENT RIGHTS, THE ACCURACY, COMPLETENESS, SAFETY, USEFULLNESS, LIKELIHOOD OF SUCCESS, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE PATENT RIGHTS OR INFORMATION SUPPLIED BY HJF, OR OF THE LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT. HJF MAKES NO REPRESENTATIONS WHATSOEVER THAT THE PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE OR ANY SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS.

9.4 Licensee represents and warrants that Licensee has not previously entered into and will not enter into any agreement with an unrelated third Person that is inconsistent with the obligations of Licensee herein, and that Licensee has full power, right and authority to enter into and carry out its obligations under this Agreement.

9.5 Licensee represents and warrants that it has not received any notice or threat of any claim, suit, action, or proceeding, and has no knowledge or reason to know of any information, that could: (a) invalidate or render unenforceable any claim of the Patent Rights; or (b) cause any claim of the Patent Rights to fail to issue or be materially limited or restricted as compared with its currently pending scope.

9.6 Each Party warrants and represents to the other Party as follows as of the Effective Date and on a continuing basis throughout the term of this Agreement that:

(a) Organization - such Party is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its incorporation;

(b) Enforceability - this Agreement constitutes the lawful, valid, and legally binding obligation of such Party, enforceable in accordance with its terms;

ARTICLE X
TERMINATION OF AGREEMENT

10.1 This Agreement, unless terminated as provided herein, shall remain in effect until the later of (a) the full end of the term or terms of all the Patent Rights on a country-by-country basis or (b) fifteen (15) years from the first sale of the Licensed Product in a given country, whichever is longer.

10.2 HJF may terminate this Agreement only in the circumstances set forth in this Section and Section 11.3(e), and any such termination shall be effective immediately upon HJF giving written notice to Licensee of any of the following unless a different time frame is specified in this Section:

(a) if Licensee does not meet any of the diligence milestone events listed in Appendix B;

(b) if Licensee does not make a payment due hereunder and fails to cure such non payment (including the payment of interest in accordance with Section 5.2(c)) within [***] days after Licensee's receipt of notice in writing of such non-payment;

(c) if Licensee defaults in its obligations under Sections 11.3(d), 11.3(e), and 11.3(f) to procure and maintain insurance and fails to remedy the situation within [***] days of Licensee's receipt of a notice in writing;

(d) if Licensee, or any of its Affiliates or sublicenses, challenges, whether as a claim, cross-claim, counterclaim, or defense, the validity or enforceability of any of the licensed Patent Rights before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction;

(e) if Licensee: is unable to pay its debts as such debts become due; makes a general assignment for the benefit of creditors; has a petition in bankruptcy or a suit seeking reorganization, liquidation, dissolution, or similar relief filed against it; or files or permits the filing of any petition or answer seeking to adjudicate itself bankrupt or insolvent, or seeking for itself any liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of Licensee or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking or consenting to the appointment of a trustee, custodian, receiver, liquidator or other similar official for Licensee or for any substantial part of its property; or takes any corporate action to authorize any of the foregoing actions;

(f) if Licensee is convicted of a felony relating to the manufacture, use, or sale of any Licensed Product or Licensed Process, or willfully omitted a material fact in the progress report, or any other report required by this Agreement; or

(g) except as provided in Section 4.1 and subsections (a), (b), (c), (d), (e) or (f) above, if Licensee defaults in the performance of any material obligations under this Agreement (including Licensee's obligations under Section 7.2 to use commercially reasonable efforts to pursue issuance of patents) and the default has not been remedied within [***] days after the date of notice in writing of such default by HJF.

10.3 Licensee shall provide, in all sublicenses granted by it under this Agreement, that Licensee's interest in such sublicenses shall at HJF's option terminate or be assigned to HJF upon termination of this Agreement by HJF in accordance with the termination rights set forth above.

10.4 Licensee may terminate this Agreement by giving [***] days advance written notice of termination to HJF, which termination shall become effective as of the end of such [***] period.

10.5 Within [***] days after termination of this Agreement by either Party, Licensee shall submit a final Royalty Report to HJF, and any and all maintenance fees and royalty payments and other fees then due shall become

payable. In addition, Licensee shall remain obligated to make, in accordance with the terms of this Agreement, royalty payments on any and all future sales of Licensed Products made but not yet sold at the time of termination, and reimburse HJF for any unreimbursed patent expenses incurred by HJF prior to the receipt of Licensee's termination notice.

10.6 Immediately upon termination pursuant to this Article X, whether by HJF or by Licensee, all licensed Patent Rights shall revert to HJF, and Licensee shall cooperate in good faith in transferring responsibility for all patent prosecution and maintenance to HJF.

10.7 Upon termination, Licensee shall pay any unpaid Pre-License Patent Expenses and promptly provide to HJF all pre-clinical data and regulatory correspondence derived during development of Licensed Products and Licensed Processes and Licensee shall grant to HJF a non-exclusive, royalty-free license, with the right to sublicense, to manufacture, use and sell improvements, including any and all know-how, to licensed Patent Rights made by Licensee during the period of this Agreement prior to such termination, to the extent that such improvements are dominated by or derived from any of the licensed Patent Rights.

10.8 Articles I and VI and Sections 2.5, 5.2, 7.1, 8.4, 10.5, 10.6, 10.7, 10.8, 11.1 through 11.7 inclusive, 11.9, 11.10, and 11.12 through 11.18 inclusive shall survive any expiration or termination of this Agreement indefinitely. Additionally, any rights or remedies arising out of a breach or violation of any terms of this Agreement will survive any expiration or termination of this Agreement. The expiration or termination of this Agreement shall not discharge either Party from any obligation that it owes to the other Party by reason of any loss, cost, damage, expense, liability, or contractual duty that occurs or arises (or the circumstances, events, or basis of which occurs or arises) prior to such expiration or termination, and shall not affect the right of either Party to institute or maintain any action for damages relating to any breach of this Agreement by the other Party prior to the date of termination. It is the intent of the Parties that any such obligation owed by a Party to the other Party arising before the date of expiration or termination (whether the same shall be known or unknown at such date, or whether the circumstances, events, or basis of the same shall be known or unknown at such date), including royalty obligations (computed in accordance with Article III) on sales made or ordered prior to the date of termination or expiration, indemnification obligations, and confidentiality obligations, shall survive the expiration or termination of this Agreement.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Rules of Construction. This Agreement is to be interpreted in accordance with the following rules of construction:

(a) Number and Gender. All definitions of terms apply equally to both the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(b) Including: Herein; Etc. The words "include," "includes," and "including" are deemed to be followed by the phrase "without limitation." The words "herein," "hereof," and "hereunder" and words of similar import refer to this Agreement (including all Appendices) in its entirety and are not limited to any part hereof, unless the context shall otherwise require. The word "or" is not exclusive and means "and/or."

(c) Sales. The terms "sold," "sell," and "sale(s)" include leases and other transfers and similar transactions for consideration.

(d) Subdivisions and Attachments. All references in this Agreement to Articles, Sections, subsections, paragraphs, and Appendices are, respectively, references to Articles, Sections, subsections, and paragraphs of, and Appendices to, this Agreement, unless otherwise specified.

(e) References to Documents and Laws. All references to this Agreement or any Appendix hereof are to it as amended, modified, and supplemented from time to time in accordance with the terms of this Agreement. All references to (i) any other agreement or instrument or (ii) any statute, law, regulation, permit, or similar item are to it as amended and supplemented from time to time (and, in the case of a statute, law or regulation, to any corresponding provisions of successor statutes, laws, or regulations), unless otherwise specified.

(f) References to Days. Any reference in this Agreement or Order issued hereunder to a "day" or number of "days" (without the explicit qualification "Business") is a reference to a calendar day or number of calendar days. If any action or notice is to be taken or given on or by a particular calendar day, and such calendar day is not a Business Day, then such action or notice may be taken or given on the next Business Day.

(g) Examples. If, in any provision of this Agreement any example is given (through the use of the words "such as," "for example," "e.g.," or otherwise) of the meaning, intent, or operation of any provision of this Agreement, such example is intended to be illustrative only and not exclusive.

(h) Currency. Except as expressly provided herein, all prices or other monetary amounts stated in this Agreement are, and all monetary amounts stated in any report to be delivered pursuant hereto shall be, stated in United States Dollars.

(i) Participation in Drafting. Both Parties and their respective legal counsel have participated, or had the opportunity to participate, in the drafting of this Agreement, and this Agreement will be construed simply and according to its fair meaning and not strictly for or against either Party.

11.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER THE PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. HJF'S AGGREGATE LIABILITY FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY LICENSEE TO HJF UNDER THIS AGREEMENT. The foregoing exclusions and limitations shall apply to all claims and actions of any kind, whether based on contract, tort (including but not limited to negligence), or any other grounds except that such exclusions and limitations shall not apply to Licensee's indemnification obligations under Section 11.3.

11.3 Indemnification and Insurance.

(a) Licensee shall indemnify, defend and hold harmless HJF and its current and former directors, board members, trustees, officers, employees, and agents and their respective successors, heirs and assigns (collectively, the "Indemnitees"), from and against any and all third party claims, liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation) (collectively "Claims") based upon, arising out of, or otherwise relating to Claims that arise out of or are related to (i) Licensee's manufacture and sale of Licensed Product, (ii) the failure of Licensee to comply with all laws, rules and/or regulations of any jurisdiction applicable to this Agreement; or (iii) the breach of any representation or warranty by Licensee in this Agreement. HJF will promptly notify Licensee within a reasonable time after it becomes aware of any Claim that may be subject to indemnification pursuant to this Section and will cooperate with and authorize Licensee to carry out the sole management and defense of such Claim. In the event HJF decides to employ its own separate counsel in connection with the sole management and defense by Licensee of the Claim, the employ of such counsel shall be at HJF's sole expense. HJF will not compromise or settle any claim, action or proceeding subject to indemnification pursuant to this Section without the prior written approval of Licensee.

(b) HJF shall indemnify, defend and hold harmless the Licensee and its current and former directors, board members, trustees, officers, employees, and agents and their respective successors, heirs and assigns (collectively, the "Licensee Indemnitees"), from and against any and all third party claims, liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation) (collectively "Claims") based upon, arising out of, or otherwise relating to Claims that arise out of or are related to the breach of any representation or warranty by HJF in this Agreement. Licensee will promptly notify HJF within a reasonable time after it becomes aware of any Claim that may be subject to indemnification pursuant to this Section and will cooperate with and authorize HJF to carry out the sole management and defense of such Claim. In the event Licensee decides to employ its own separate counsel in connection with the sole management and defense by HJF of the Claim, the employ of such counsel shall be at Licensee's sole expense. Licensee will not compromise or settle any claim, action or proceeding subject to indemnification pursuant to this Section without the prior written approval of HJF.

(c) The indemnifying Party shall, at its own expense, provide attorneys reasonably acceptable to the other to defend against any actions brought or filed with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

(d) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by any sublicensee or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $[***] per incident and $[***] annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process, or service, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HJF shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions that are in excess of $[***]annual aggregate) such self-insurance program must be acceptable to HJF in its sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limitation of Licensee's liability with respect to its indemnification under this Agreement.

(e) Licensee shall provide HJF with written evidence of such insurance upon request of HJF. Licensee shall provide HJF with written notice at least [***] days prior to the cancellation, non-renewal, or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such [***] day period, HJF shall have the right to terminate this Agreement in accordance with Section 10.2 (c).

(f) Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement (i) during the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Licensee or by a sublicensee or agent of Licensee and (ii) a period after the period referred to in (f)(i) above, which period in no event shall be less than [***] years.

11.4 Limitation on Advertising and Publicity. Licensee shall not use HJF's or USU's name or insignia, or the name or insignia of the U.S. Government or any agency thereof, or any adaptation of the foregoing, or the name of any of HJF's or USU's inventors, in any press release, public announcement, advertising, promotional, or sales literature without the prior written approval of HJF or USU, as the case may be.

11.5 No Assignment. Without the prior written approval of HJF in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by Licensee to any person whether voluntarily or involuntarily, by operation of law, or otherwise except that Licensee may assign this Agreement in connection with a sale or transfer of all or substantially all of the relevant business or assets of Licensee without such consent and may assign this Agreement to an Affiliate without such consent. This Agreement shall be binding upon the respective successors, legal representatives, and assignees of HJF and Licensee.

11.6 Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of Maryland, as to all matters, including matters of validity, construction, effect, performance, and remedies, irrespective of any contrary choice of law that otherwise would be applicable under the choice of laws principles of any jurisdiction.

11.7 Compliance with Laws and Regulations. Licensee shall comply with all applicable laws and regulations, including United States laws and regulations controlling exports, if applicable. Licensee agrees that it will be solely responsible for any violation of applicable laws or regulations by Licensee or sublicensees,

11.8 Regulatory Approvals: Patent Markings. Licensee agrees (i) to obtain all regulatory approvals required for the manufacture and sale of Licensed Products and Licensed Processes and (ii) to utilize appropriate patent marking on such Licensed Products. Licensee also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.

11.9 Confidential Information and Intellectual Property. Except as specifically required to comply with obligations set forth in this Agreement, neither Party shall be obligated to disclose or furnish to the other Party any Confidential Information of such first Party or any confidential or proprietary information, technology, or intellectual property of any third party in such first Party's possession or control. If, however, the Parties have heretofore entered or hereafter enter into a confidential information nondisclosure agreement or similar agreement (the "NDA"), neither Party may terminate the NDA prior to the termination or expiration of this Agreement. If the Parties have not entered into an NDA, each Party agrees, for the greater of a period of five (5) years after each disclosure or during the pendency of this Agreement, to maintain in confidence all Confidential Information disclosed to it by the other Party and to protect such Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the receiving Party uses to protect its own similar confidential information. The obligations of confidentiality and non-use set forth in this Agreement shall not apply with respect to any information that a Party is required to disclose or produce pursuant to applicable law, court order or other valid legal process provided that the disclosing Party promptly notifies the other Party prior to such required disclosure, discloses such information only to the extent so required and cooperates reasonably with the other Party's efforts to contest or limit the scope of such disclosure.

11.10 Headings. The article, section, and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define, or limit the scope, extent, or intent of this Agreement.

11.11 Counterpart Execution. This Agreement and any modification or amendment thereof may be executed in counterparts, both of which shall be considered one and the same agreement, and shall become effective when such counterparts have been signed by each of the Parties and delivered to the other Party.

11.12 Waivers; Remedies Generally. The observance of any term of this Agreement may be waived (whether generally or in a particular instance and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver will be effective only if in a writing signed by the Party against which such waiver is to be asserted, Except as otherwise provided in this Agreement, no failure or delay of either Party in exercising any power, right, or remedy under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any such right, power, or remedy, preclude any other or further exercise thereof or the exercise of any other right, power, or remedy. A waiver by either Party shall be limited to the specific instance in which it is given and, therefore, any waiver by either Party of any obligation of the other Party under or breach by the other Party of this Agreement or of any power, right, or remedy of the waiving Party shall not be a waiver of any other obligation or further or future performance of the same obligation, of any other or succeeding breach, of any other or further exercise of such power, right, or remedy or any other power, right, or remedy.

11.13 Severability. To the extent that any provision of this Agreement shall be judicially unenforceable in any one or more jurisdictions, such provision shall not be affected with respect to any other jurisdiction, each provision with respect to each jurisdiction being construed as several and independent. If any term or provision of this

Agreement or the application thereof to any person or circumstance is, to any extent, declared or found to be illegal, unenforceable, or void, then both Parties will be relieved of all obligations arising under such term or provision, but only to the extent that such term or provision is illegal, unenforceable, or void, it being the intent and agreement of the Parties that this Agreement will be deemed amended by modifying such term or provision to the extent necessary to make it legal and enforceable while preserving its intent or, if that is not possible, by substituting therefor another term or provision that is legal and enforceable and achieves the same objective. If the remainder of this Agreement will not be affected by such declaration or finding and is capable of substantial performance, then each term and provision not so affected will be enforced to the extent permitted by law. If necessary to effect the intent of the Parties, the Parties will negotiate in good faith to amend this Agreement to replace the unenforceable language with enforceable language that as closely as possible reflects such intent and to amend any other term or provision thereby rendered incapable of substantial performance or otherwise affected thereby to the extent necessary to permit the practical realization, insofar as legally possible, of the intent of the Parties.

11.14 Relationship of the Parties; Disclaimer of Agency.

(a) Independent Contractors. In entering into and carrying out this Agreement, the Parties will be acting solely as independent contractors. Nothing in this Agreement creates, has created, or will create any partnership joint venture, or other business association between the Parties, nor any duties or responsibilities of partners, venturers, or members of a business association.

(b) No Agency. Except for provisions in this Agreement expressly authorizing one Party to act for the other, this Agreement will not constitute either Party as a legal representative or agent of the other Party, nor will either Party have the right or authority to assume, create, or incur any liability or any obligation of any kind, expressed or implied, against or in the name or on behalf of the other Party unless otherwise expressly permitted by such Party.

11.15 No Third Party Beneficiaries. The representations, warranties, covenants, and undertakings contained in this Agreement are for the sole benefit of the Parties, their sublicensees, and the Parties' permitted successors and assigns and shall not be construed as creating any third party beneficiaries of this Agreement or as conferring any rights whatsoever on any third party.

11.16 Notices. Unless otherwise expressly agreed by the Party receiving notice, any notice, demand, or other communication required or permitted to be given by either Party under any provision of this Agreement must be in writing, in the English language, and mailed (certified or registered mail, postage prepaid, return receipt requested) or sent by hand or overnight courier, or by facsimile (with acknowledgment received), charges prepaid and addressed to the intended recipient at such Party's address set forth below, or to such other address or number as such Party may from time to time specify by notice to the other Party as provided in this Section. All notices and other communications given in accordance with the provisions of this Agreement will be deemed to have been given and received (i) when actually delivered by hand, by mail, or by courier, or (ii) when transmitted by facsimile (with acknowledgment received and a copy of such notice is sent no later than the next Business Day by a reliable overnight or two-day courier service, with acknowledgment of receipt).

If to Licensee:

TeraImmune, Inc.
ATTN: Jihoon Park, Chief Executive Officer
9610 Medical Center Dr., Suite 200, Maryland 20852

with a copy to:

Rubin and Rudman LLP
800 Connecticut Ave. NW
Washington DC 20006
Attention: Judith U. Kim, Esq.

Ph: (240) 356-1511
E-mail: jkim@rubinrudman.com

If to HJF:

The Henry M. Jackson Foundation for
the Advancement of Military Medicine, Inc.
ATTN: Chief Technology Officer
6720A Rockledge Drive, Suite 100, Bethesda, MD 20817

11.17 Disputes.

(a) In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the Parties shall try to settle such conflict amicably between themselves. Subject to the exclusions and limitations stated in the final sentence of this Section, any such conflict that the Parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association unless the Parties agree to use an alternate dispute resolution organization, except that only one arbitrator will be selected, and the arbitrator must be in the Washington D.C. Metropolitan Area. In addition, the arbitrator, before being selected, must agree to issue the ruling on the dispute not later than 180 calendar days from the initial filing for arbitration, and shall have no authority to make any award for damages excluded in the agreement, nor for attorneys' fees. Arbitration discovery, to the extent permitted at all, shall be limited. If the Parties do not agree to the scope and nature of discovery, then the arbitrator shall decide the extent to which discovery is allowed. If the arbitrator must decide, then no interrogatories or requests for admission shall be allowed, and depositions, to the extent that any at all are permitted based on a showing of substantial need, shall be limited to no more than three per Party, including no more than one corporate deposition, if allowed. No motions practice will be allowed. Unless the Parties agree, the arbitrator shall decide whether to require pre-hearing exchanges of exhibits and summaries of witness testimony upon which each Party is relying, and proposed rulings and remedies on each issue.

(b) A demand for arbitration or commencement of litigation shall be filed within a reasonable time after the controversy or claim has arisen, and in no event later than the earlier of: (a) six months after the termination or purported termination of this Agreement, or (b) the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitations. For the avoidance of doubt, failure to demand arbitration or commence litigation on an issue arising out of or relating to this Agreement or the breach thereof within the time period set forth in the preceding sentence absolutely precludes the later arbitration or litigation of such issue. Such arbitration shall be held in Montgomery County, Maryland. The award through arbitration shall be final and binding. Either Party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either Party may, without recourse to arbitration, assert against the other Party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant. In addition, notwithstanding the foregoing, disputes over ownership of intellectual property and claims for damages in excess of one million dollars are excluded from arbitration and either Party may commence an action for such disputes in a state court of competent jurisdiction in Montgomery County, Maryland, or, if jurisdiction is proper in federal court, in the appropriate federal District Court for the District of Maryland, and both Parties hereby consent to personal jurisdiction in such state and federal courts in Maryland.

11.18 Entire Agreement; Modifications. This Agreement constitutes the complete agreement between the Parties concerning the subject matter hereof and replaces any prior oral or written communications between the Parties. There are no conditions, understandings, agreements, representations, or warranties, express or implied, that are not specified herein, and neither Party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed by the Parties in writing. Any purported modification or amendment of the express terms or provisions of this Agreement shall be effective only if contained in a written instrument signed by each Party.

SIGNATURES ON THE FOLLOWING PAGE

HJF AND LICENSEE HAVE READ THIS AGREEMENT INCLUDING ALL APPENDICES HERETO AND AGREE TO BE BOUND BY ALL THE TERMS AND CONDITIONS HEREOF AND THEREOF.

IN WITNESS WHEREOF, the Parties have entered into this License Agreement as of the date first above set forth.

THE HENRY M. JACKSON FOUNDATION FOR THE
ADVANCEMENT OF MILITARY MEDICINE, INC.

/s/ Qi “Soso” Yang
Signature

Qi “Soso” Yang, Director, OSP
Name & Title

08/02/2019
Date

TERAIMMUNE, INC.

/s/ Jihoon Park
Signature

Jihoon Park, Chief Executive Officer
Name & Title

08/08/2019
Date

SCHEDULE A
PATENT RIGHTS

[***]

APPENDIX B
DILIGENCE MILESTONES & MILESTONE FEES

[***]

Exhibit 10.8

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and the registrant customarily and actually treats as private and confidential.

PUBLIC HEALTH SERVICE

BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is based on the model Biological Material License Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

National Cancer Institute

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

TeraImmune, Inc.,

hereinafter referred to as the "**Licensee**",

having offices at 9610 Medical Center Dr., Suite 200, Rockville, MD 20850,

created and operating under the laws of Delaware.

Tax ID No.:_ [***]

1. Definitions:

(a) "Affiliate(s)" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the Licensee. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

(b) "Government" means the government of the United States of America.

(c) "FDA" means the Food and Drug Administration.

(d) "Materials" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof: retroviral vector pMSGV1, as described in HHS reference E-123-2014-0 and developed in the laboratory of Dr. Richard Morgan at the IC.

(e) "Licensed Field of Use" means development and commercialization of engineered autologous T cell therapy products for the treatment of hemophilia A in humans.

(f) "Licensed Products" means T cell therapy product(s) transduced with the Materials.

(g) "Net Sales" means the total gross receipts by the Licensee for sales of Licensed Products or from income from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, or for the cost of collections.

2. The Licensee desires to obtain a license from the IC to use the Materials provided under this Agreement in its commercial research or product development and marketing activities. The Licensee represents that it has the facilities, personnel, and expertise to use the Materials or the Licensed Products for commercial purposes and agrees to expend reasonable efforts and resources to develop the Materials or the Licensed Products for commercial use or commercial research.

3. The IC hereby grants to the Licensee:

(a) a worldwide, non-exclusive license to make, have made, and use the Materials or the Licensed Products in the Licensed Field of Use; and

(b) a worldwide, non-exclusive license to sell and have sold, to offer to sell and to import the Licensed Products in the Licensed Field of Use.

4. In consideration of the grant in Paragraph 3, the Licensee hereby agrees to make the following payments to the IC:

(a) Within [***] days of its execution of this Agreement, a non-creditable, nonrefundable license issue royalty of [***] dollars ($[***]).

(b) The first minimum annual royalty of [***] dollars ($[***]) is due [***] days of the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1;

(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year;

(d) An earned royalty of [***] percent ([***]%) of Net Sales, which shall be due and payable within [***] days of the end of each calendar year; and

(e) All payments required under this Agreement shall be paid in U.S. dollars and payment options are listed in Appendix C. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in The Wall Street Journal on the day that the payment is due.

i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the Licensee; and

ii) Additional royalties may be assessed by the IC on any payment that is more than [***] days overdue at the rate of [***] percent ([***]%) per month. This [***]percent ([***]%) per month rate may be applied retroactively from the original due date until the date of receipt by the IC of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the IC from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by the IC of the license issue royalty and the prorated first year minimum annual royalty and verification of these royalties, the IC agrees to provide the Licensee with samples of the Materials, as available, and to replace these Materials, as available, at reasonable cost, in the event of their unintentional destruction. The IC shall provide the Materials to the Licensee at the Licensee's expense and as specified in Appendix A.

6. The Licensee agrees to make written reports to the IC within [***] days of December 31 for each calendar year. This report shall state: the number, description, and aggregate Net Sales of Licensed Products made, sold, or otherwise disposed of; the total gross income received by the Licensee from leasing, renting, or otherwise making Licensed Products available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due to the IC pursuant to Paragraph 4(d) and as shown in the example in Appendix B. The Licensee shall submit each report to the IC at the Mailing Address for Agreement notices indicated on the Signature Page.

7. The Licensee agrees to supply the laboratory of Dr. Steven Rosenberg at the IC at no charge, reasonable quantities of Materials or the Licensed Products that the Licensee makes, uses, sells, or offers for sale or otherwise makes available for public use. The Licensee also agrees to supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the Licensed Products or their packaging for educational and display purposes only.

8. This Agreement shall become effective on the date when the last party to sign has executed this Agreement, unless the provisions of Paragraph 27 are not fulfilled, and shall expire ten (10) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17.

9. As part of the Licensee's performance under this Agreement, the Licensee agrees to make the Licensed Products available to the public within eight (8) years from the effective date of this Agreement.

10. The Licensee agrees to retain control over the Materials and the Licensed Products, and not to distribute them to third parties without the prior written consent of the IC except as provided in Paragraph 3.

11. This Agreement does not preclude the IC from distributing the Materials or the Licensed Products to third parties for research or commercial purposes.

12. By this Agreement, the IC grants no patent rights expressly or by implication to any anticipated or pending IC patent applications or issued patents.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO THE LICENSEE UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR THE LICENSED PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. The Licensee accepts license rights to the Materials and the Licensed Products “as is”, and the IC does not offer any guarantee of any kind.

14. Licensee agrees to indemnify and hold harmless the Government from any claims, costs, damages, or losses that may arise from or through the Licensee’s use of the Materials or the Licensed Products. The Licensee further agrees that it shall not by its action bring the Government into any lawsuit involving the Materials or the Licensed Products.

15. The Licensee agrees in its use of the Materials or the Licensed Products to comply with all applicable statutes, regulations, and guidelines, including NIH and HHS regulations and guidelines. The Licensee agrees not to use the Materials or the Licensed Products for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The Licensee agrees not to use the Materials or the Licensed Products for research involving human subjects or clinical trials outside of the United States without notifying the IC, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the IC of research involving human subjects or clinical trials outside of the United States shall be given no later than [***] days prior to commencement of such research or trials.

16. The Licensee may terminate this Agreement upon [***] days written notice to the IC but only after [***] days from the effective date of this Agreement.

17. The IC may terminate this Agreement if the Licensee is in default in the performance of any material obligation under this Agreement, and if the default has not been remedied within [***] days after the date of written notice by the IC of the default.

18. Within [***] days of the termination or expiration of this Agreement, the Licensee agrees to return all Materials and the Licensed Products to the IC or provide the IC with written certification of their destruction.

19. Within [***] days of termination or expiration of this Agreement, the Licensee agrees to submit a final report to the IC, and to submit to the IC payment of any royalties due. The Licensee may not be granted additional IC licenses if this final reporting requirement is not fulfilled.

20. The Licensee is encouraged to publish the results of its research projects using the Materials or the Licensed Products. In all oral presentations or written publications concerning the Materials or the Licensed Products, the Licensee shall acknowledge the contribution of Dr. Richard Morgan at the IC supplying the Materials, unless requested otherwise by the IC or Dr. Richard Morgan.

21. All plans and reports required by this Agreement shall be treated by the IC as commercial and financial information obtained from a person and as privileged and confidential and, to the extent permitted by law, not subject to disclosure under the Freedom of Information Act, 5 U.S.C. §552.

22. This Agreement shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Licensee agrees to be subject to the jurisdiction of U.S. courts.

23. This Agreement constitutes the entire understanding of the IC and the Licensee and supersedes ail prior agreements and understandings with respect to the Materials or the Licensed Products.

24. The provisions of this Agreement are severable, and in the event that any provision of the Agreement shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this Agreement, shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

25. Paragraphs 4, 13, 14, 18, 19, 20, 21 and 25 of this Agreement shall survive termination or expiration of this Agreement.

26. This Agreement shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the Licensee's Affiliate(s) without the prior written consent of the IC. The parties agree that the identity of the parties is material to the formation of this Agreement and that the obligations under this Agreement are nondelegable. In the event that the IC approves a proposed assignment, the Licensee shall pay the IC, as an additional royalty, [***] percent ([***]%) of the fair market value of any consideration received for any assignment of this Agreement within [***] days of the assignment.

27. The terms and conditions of this Agreement shall, at the IC's sole option, be considered by the IC to be withdrawn from the Licensee's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Licensee and a fully executed original is received by the IC within [***]days from the date of the IC signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

THE IC BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the IC:

/s/ Susan R. Rucker — 08/15/2019
Name: Susan S. Rucker, for Richard U. Rodriguez, MBA — Date
Title: Associate Director
Office: Technology Transfer Center, National Cancer Institute
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

[***]

For the Licensee (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Licensee made or referred to in this document are truthful and accurate.):

by:

/s/ Jihoon Park — 08/26/2019
Signature of Authorized Official — Date
Jihoon Park, Ph.D.
Printed Name
Chief Executive Officer
Title

I. Official and Mailing Address for Agreement notices:

Jihoon Park
Name
Chief Operating Officer
Title

Mailing Address:
TeraImmune, Inc.
9610 Medical Center Dr., Suite 200
Rockville, MD 20850

Email Address: [***]

Phone: 301-646-8683

Fax:

II. Official and Mailing Address for Financial notices (the Licensee's contact person for royalty payments)

Jihoon Park
Name
Chief Operating Officer
Title

Mailing Address:
TeraImmune, Inc.
9610 Medical Center Dr., Suite 200
Rockville, MD 20850

Email Address: [***]
Phone: 301-646-8683
Fax:

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

Exhibit 31.1

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, 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 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 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 16, 2023

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Jillian Dilmore, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, 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 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 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 16, 2023

/s/ Jillian Dilmore
Jillian Dilmore
Corporate Controller
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 Baudax Bio, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 16, 2023

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Jillian Dilmore
Jillian Dilmore
Corporate Controller
(Principal Financial and Accounting Officer)