Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

Or

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

For the transition period from to

Commission file number: 001-36080

IVERIC bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-8185347**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8 Sylvan Way **Parsippany, NJ**	**07054**
(Address of principal executive offices)	(Zip Code)

(609) 474-6755

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	ISEE	The Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

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

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

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

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

As of May 1, 2023 there were 137,782,748 shares of Common Stock, $0.001 par value per share, outstanding.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements 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," "goals," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- statements related to the transactions contemplated by the Agreement and Plan of Merger, dated as of April 28, 2023, or the Merger Agreement, among us, Astellas US Holding, Inc., a Delaware corporation, or Astellas, Berry Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Astellas, or Merger Sub, and solely as provided by Section 8.10(b) of the Merger Agreement, Astellas Pharma Inc., a company organized under the laws of Japan, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into our company, or the Merger, with our company surviving the Merger as a wholly owned subsidiary of Astellas, including our expectations regarding the consummation of the Merger within the timeframe anticipated, or at all;
- the potential benefits of our business plan and strategy, including our goal to deliver treatment options for various stages of age-related macular degeneration (AMD);
- our expectations regarding the impact of results from GATHER1, our completed Phase 3 clinical trial evaluating avacincaptad pegol (ACP) for the treatment of Geographic Atrophy (GA) secondary to AMD, and from GATHER2, our ongoing Phase 3 clinical trial evaluating ACP for the treatment of GA secondary to AMD, on our business and regulatory strategy, including, the timing and response to our new drug application (NDA) submitted to the U.S. Food and Drug Administration (FDA), our plans to submit marketing authorization applications to the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), and our expectations for using ACP for the treatment of intermediate AMD;
- the timing, costs, conduct and outcome of GATHER2, including expectations regarding patient retention and the safety profile of ACP, including from our open-label extension study for patients who completed the GATHER2 trial, and expectations regarding the potential for ACP to receive regulatory approval for the treatment of GA based on the clinical trial results we have received to date;
- our plans and strategy for the potential commercialization of ACP, including hiring of medical affairs and commercialization personnel, building a commercialization infrastructure, including sales, marketing and distribution capabilities, and our expectations regarding the market dynamics for treatments for GA and other commercial matters;
- our ability to establish and maintain capabilities and capacity for the manufacture of ACP and our other product candidates, including scale up and validation of the manufacturing process for ACP drug substance and drug product, and securing the supply of the polyethylene glycol (PEG) starting material and other materials for our expected manufacturing needs and securing the supply of ACP drug substance, drug product and finished goods for our expected needs;
- our plans for evaluating, obtaining rights to, developing and potentially commercializing new formulations of ACP with the silica-based sustained release technology we in-licensed from DelSiTech Ltd. (DelSiTech) and other sustained release delivery technologies for ACP;
- the timing, costs, conduct and outcome of STAR, our ongoing Phase 2b screening trial evaluating ACP for the treatment of autosomal recessive Stargardt disease, including expectations regarding the recruitment of additional patients for this trial;
- our estimates regarding expenses, future revenues and debt service obligations, the sufficiency of our cash resources and our capital requirements and need for, and ability to obtain, additional financing;

- the timing, costs, conduct and outcome of our ongoing clinical trials, including statements regarding the timing of the initiation and completion of, and the receipt of results from, such clinical trials, the costs to conduct such clinical trials, and the impact of the results of such clinical trials on our business strategy;
- the timing, costs, conduct and outcome of our ongoing and planned research and preclinical development activities, including statements regarding the timing of the initiation and completion of, and the receipt of results from, such activities, the costs to conduct such activities, and the impact of the results of such activities on our business strategy;
- the timing of and our ability to submit investigational new drug applications for, and to submit new drug applications or marketing authorization applications for and to obtain marketing approval of our product candidates, and the ability of our product candidates to meet existing or future regulatory standards;
- the potential advantages of our product candidates and other technologies that we are pursuing, including our hypotheses regarding complement factor C5 inhibition and HtrA1 inhibition as potentially relevant mechanisms of action to treat GA and other stages of AMD, and of gene therapy, including the use of minigenes;
- our estimates regarding the number of patients affected by the diseases our product candidates and development programs are intended to treat;
- our estimates regarding the potential market opportunity for our product candidates, including our ability to obtain coverage and reimbursement for those product candidates, if approved;
- the rate and degree of potential market acceptance and clinical utility of our product candidates, if approved;
- the potential receipt of revenues from future sales of our product candidates, if approved;
- our personnel and human capital resources;
- our plans and ability to acquire rights to additional product candidates or technologies to treat retinal diseases, including additional sustained release delivery technologies for ACP;
- our intellectual property position;
- the impact of existing and new governmental laws and regulations; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and our stockholders should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission, or SEC, on March 1, 2023, and in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" sections that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, licenses, dispositions, joint ventures or investments we may make. In particular, except as otherwise indicated, our forward-looking statements do not assume the consummation of the proposed acquisition of our company by Astellas. If the Merger is consummated, many of the forward-looking statements contained in this Quarterly Report on Form 10-Q would no longer be applicable.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q and our other periodic reports, completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

In connection with the proposed acquisition by Astellas, we will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed acquisition. This document is not a substitute for the proxy statement or any other document which we may file with the SEC. The definitive proxy statement will be mailed to our stockholders in connection with the proposed acquisition. This Quarterly Report on Form 10-Q is not a substitute for the proxy statement or any other document that may be filed by us with the SEC. BEFORE MAKING ANY VOTING DECISION, OUR INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED ACQUISITION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION. Any vote in respect of resolutions to be proposed at our stockholder meeting to approve the proposed acquisition or other responses in relation to the proposed acquisition should be made only on the basis of the information contained in our proxy statement relating to the proposed acquisition. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at www.sec.gov, and all documents filed by us with the SEC are available to all of our stockholders free of charge at https://investors.ivericbio.com/financial-information/sec-filings or by contacting our investor relations department at the following:

IVERIC bio, Inc.
Kathy Galante
Senior Vice President, Investor Relations
kathy.galante@ivericbio.com

We, and our directors, executive officers and other members of management and certain other people may be deemed to be participants in the solicitation of proxies in connection with the proposed acquisition by Astellas. Information about our directors and executive officers is included in the proxy statement for our 2023 annual meeting of stockholders, filed with the SEC on April 5, 2023. Additional information regarding these persons and their interests in the proposed acquisition will be included in the proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents, when available, can be obtained free of charge from the sources indicated above.

USE OF TRADEMARKS

The trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this Quarterly Report on Form 10-Q after their first reference in this Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

IVERIC bio, Inc.
Condensed Unaudited Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 467,572	$ 476,304
Available for sale securities	132,349	170,531
Prepaid expenses and other current assets	11,622	15,991
Total current assets	611,543	662,826
Property and equipment, net	1,109	946
Right-of-use asset, net	755	1,182
Other assets	—	1,869
Total assets	$ 613,407	$ 666,823
Liabilities and Stockholders' Equity		
Current liabilities		
Accrued research and development expenses	$ 20,574	$ 11,555
Accounts payable and accrued expenses	18,026	22,843
Lease liability	774	1,189
Total current liabilities	39,374	35,587
Lease liability, non-current	—	11
Debt, non-current	96,987	96,568
Total liabilities	136,361	132,166
Stockholders' equity		
Preferred stock—$0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock—$0.001 par value, 200,000,000 shares authorized, 137,249,579 and 136,639,687 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	137	137
Additional paid-in capital	1,414,043	1,399,555
Accumulated deficit	(937,035)	(864,806)
Accumulated other comprehensive income	(99)	(229)
Total stockholders' equity	477,046	534,657
Total liabilities and stockholders' equity	$ 613,407	$ 666,823

The accompanying unaudited notes are an integral part of these financial statements.

IVERIC bio, Inc.
Condensed Unaudited Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 42,083	$ 22,557
General and administrative	31,758	12,113
Total operating expenses	73,841	34,670
Loss from operations	(73,841)	(34,670)
Interest income, net	3,461	133
Other (expense) income, net	(1,849)	1
Loss before income tax benefit	(72,229)	(34,536)
Income tax benefit	—	—
Net loss	$ (72,229)	$ (34,536)
Comprehensive loss	$ (72,099)	$ (34,840)
Net loss per common share:		
Basic and diluted	$ (0.53)	$ (0.29)
Weighted average common shares outstanding:		
Basic and diluted	137,087	118,755

The accompanying unaudited notes are an integral part of these financial statements.

IVERIC bio, Inc.

Condensed Unaudited Consolidated Statements of Stockholders' Equity

(in thousands)

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	—	$ —	136,640	$ 137	$ 1,399,555	$ (864,806)	$ (229)	$ 534,657
Issuance of common stock under employee stock compensation plans	—	—	610	—	2,589	—	—	2,589
Share-based compensation	—	—	—	—	11,899	—	—	11,899
Net loss	—	—	—	—	—	(72,229)	—	(72,229)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	130	130
Balance at March 31, 2023	—	$ —	137,250	$ 137	$ 1,414,043	$ (937,035)	$ (99)	$ 477,046

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	—	$ —	115,277	$ 115	$ 1,040,098	$ (679,595)	$ (90)	$ 360,528
Issuance of common stock under employee stock compensation plans	—	—	697	1	2,079	—	—	2,080
Share-based compensation	—	—	—	—	5,386	—	—	5,386
Net loss	—	—	—	—	—	(34,536)	—	(34,536)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	(304)	(304)
Balance at March 31, 2022	—	$ —	115,974	$ 116	$ 1,047,563	$ (714,131)	$ (394)	$ 333,154

The accompanying unaudited notes are an integral part of these financial statements.

IVERIC bio, Inc.

Condensed Unaudited Consolidated Statements of Cash Flows

(in thousands)

	Three Months Ended March 31,	
	2023	2022
Operating Activities		
Net loss	$ (72,229)	$ (34,536)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and other expense	70	21
Amortization and accretion of term loan related costs	419	—
Amortization of premium and discounts on investment securities	(1,289)	300
Share-based compensation	11,899	5,386
Changes in operating assets and liabilities:		
Prepaid expense and other assets	6,238	435
Accrued interest receivable	96	(66)
Accrued research and development expenses	9,019	(1,486)
Accounts payable and accrued expenses	(4,817)	(7,562)
Change in working capital	1	(4)
Net cash used in operating activities	(50,593)	(37,512)
Investing Activities		
Purchase of marketable securities	—	(48,897)
Purchase of property and equipment	(233)	(116)
Maturities of marketable securities	39,505	14,865
Net cash provided by (used in) investing activities	39,272	(34,148)
Financing Activities		
Proceeds from employee stock plan purchases	2,589	2,080
Net cash provided by financing activities	2,589	2,080
Net decrease in cash and cash equivalents	(8,732)	(69,580)
Cash and cash equivalents		
Beginning of period	476,304	261,447
End of period	$ 467,572	$ 191,867
Supplemental disclosure of cash paid		
Interest expense paid in cash	$ 2,406	$ —

The accompanying unaudited notes are an integral part of these financial statements.

IVERIC bio, Inc.
Notes to Condensed Unaudited Consolidated Financial Statements
(in thousands, except per share data)

1. Business

Description of Business and Organization

IVERIC bio, Inc. (the "Company") is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe and effective treatments designed to address debilitating retinal diseases, including earlier stages of age-related macular degeneration ("AMD").

On April 28, 2023, the Company, Astellas US Holding, Inc., a Delaware corporation ("Astellas"), Berry Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Astellas ("Merger Sub"), and solely as provided by Section 8.10(b) of the Merger Agreement, Astellas Pharma Inc., a company organized under the laws of Japan ("Guarantor"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), discussed further in Note 11, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly owned subsidiary of Astellas. Consummation of the Merger is subject to customary closing conditions, including, without limitation, obtaining the required regulatory approvals and approval by the Company's stockholders.

The Company's lead asset is its clinical stage product candidate avacincaptad pegol (also referred to as ACP), a complement C5 inhibitor. It is currently targeting the following diseases with avacincaptad pegol:

- Geographic Atrophy ("GA"), which is the advanced stage of AMD, and is characterized by marked thinning or atrophy of retinal tissue, leading to irreversible loss of vision;
- intermediate AMD, which is an earlier stage of AMD; and
- autosomal recessive Stargardt disease ("STGD1"), which is an orphan inherited condition characterized by progressive damage to the central portion of the retina (the "macula") and other retinal tissue, leading to loss of vision.

In October 2019, the Company announced positive 12-month data for GATHER1, its first Phase 3 clinical trial evaluating avacincaptad pegol for the treatment of GA secondary to AMD. In GATHER1, 286 patients were randomized to receive various doses of avacincaptad pegol, including avacincaptad pegol 2 mg, or sham control. The Company observed a 27.7% (p-value = 0.0063) reduction in the mean rate of growth (slope) estimated based on GA area between the avacincaptad pegol 2 mg group and the corresponding sham control group over 12 months, when performing the primary analysis, and a 35.4% (p-value = 0.0050) reduction in the mean rate of growth (slope) estimated based on GA area between the two groups over 12 months, when performing the supportive analysis. These results are based on a post-hoc analysis of the GATHER1 data using the U.S. Food and Drug Administration ("FDA") preferred primary efficacy endpoint analysis from the Company's Special Protocol Assessment ("SPA"), which is described further below. The Company analyzed the endpoint by using the square root transformation of the GA area, which it refers to as the primary analysis, and the Company analyzed the endpoint by using the observed GA area (without square root transformation), which it refers to as the supportive analysis. In GATHER1, through month 12, the Company did not observe any events of endophthalmitis or ischemic optic neuropathy events, and only one case of intraocular inflammation, which was mild and transient and reported as related to the injection procedure. The incidence of choroidal neovascularization ("CNV") in the study eye through month 12 was 6 patients (9.0%) in the avacincaptad pegol 2 mg group and 3 patients (2.7%) in the corresponding sham control group.

In June 2020, the Company started enrolling patients in GATHER2, its second Phase 3 clinical trial evaluating avacincaptad pegol for the treatment of GA secondary to AMD. In July 2021, the Company received a written agreement from the FDA under the SPA for the overall design of GATHER2. The SPA is a procedure by which the FDA provides a clinical trial sponsor with an official evaluation and written guidance on the design of a proposed protocol intended to form the basis for a new drug application ("NDA"). In connection with our SPA, the FDA recommended, and the Company accepted, modifying the primary efficacy endpoint for the GATHER2 trial from the mean rate of change in GA area over 12 months measured by fundus autofluorescence ("FAF") at three timepoints: baseline, month 6 and month 12, to the mean rate of growth (slope) estimated based on GA area measured by FAF in at least three timepoints: baseline, month 6 and month 12.

In September 2022, the Company announced positive 12-month top-line data for GATHER2. In GATHER2, 448 patients were randomized on a 1:1 basis to receive avacincaptad pegol 2 mg or sham control over the first 12 months of the trial. At 12

months, the Company measured the primary efficacy endpoint in accordance with the SPA. In GATHER2, the Company observed a 14.3% (p-value = 0.0064) reduction in the mean rate of growth (slope) in GA area between the two groups at 12 months with the primary analysis, and a 17.7% (p-value = 0.0039) reduction in the mean rate of growth (slope) in GA area between the two groups at 12 months with the supportive analysis. The Company did not observe any events of endophthalmitis, intraocular inflammation events, events of vasculitis or ischemic optic neuropathy events through month 12, and the incidence of choroidal neovascularization ("CNV") in the study eye through month 12 was 15 patients (6.7%) in the avacincaptad pegol 2 mg group and 9 patients (4.1%) in the sham control group.

In March 2023, the Company announced results from an exploratory time-to-event analysis from the GATHER1 and GATHER2 clinical trials evaluating reduction in vision loss with avacincaptad pegol 2 mg versus sham treatment. The GATHER1 and GATHER2 clinical trials were designed to evaluate the rate of GA lesion growth in patients with GA secondary to AMD. The post-hoc analysis for vision loss from these pivotal trials signals up to a 59% reduction in rate of vision loss with avacincaptad pegol 2 mg compared to sham treatment at 12 months. The results were consistent in the GATHER1 and GATHER2 clinical trials independently, signaling a 44% reduction (Hazard Ratio 0.56 with 95% CI, 0.15-2.06) and a 59% percent reduction (Hazard Ratio 0.41 with 95% CI, 0.17-1.00) respectively in the rate of vision loss with avacincaptad pegol 2 mg compared to sham over the first 12 months of treatment. In a combined analysis of GATHER1 and GATHER2, patients treated with avacincaptad pegol 2 mg experienced a 56% reduction (Hazard Ratio 0.44, with 95% CI, 0.21-0.92) in the rate of vision loss compared to sham over the first 12 months of treatment. Vision loss in this analysis was defined as a loss of ≥15 letters (EDTRS) in best corrected visual acuity ("BCVA") from baseline measured at any two consecutive visits up to month 12.

The Company believes that with the statistically significant results from its GATHER1 and GATHER2 trials and the safety profile of avacincaptad pegol to date, it has sufficient data from two independent, adequate and well-controlled pivotal clinical trials of avacincaptad pegol in GA secondary to AMD to support an application for marketing approval. In November 2022, the FDA granted breakthrough therapy designation to ACP for the treatment of GA secondary to AMD. In December 2022, the Company completed the rolling submission of its NDA to the FDA for marketing approval of avacincaptad pegol for the treatment of GA secondary to AMD. In February 2023, the FDA accepted its NDA for filing and granted priority review with a Prescription Drug User Fee Act ("PDUFA") target action date of August 19, 2023.

In addition to avacincaptad pegol, the Company is developing its preclinical product candidate IC-500, a High temperature requirement A serine peptidase 1 protein ("HtrA1") inhibitor, for GA secondary to AMD and potentially other age-related retinal diseases.

The Company's portfolio also includes several ongoing gene therapy research programs, each of which uses adeno-associated virus ("AAV") for gene delivery. These AAV mediated gene therapy programs are targeting the following orphan inherited retinal diseases ("IRDs"):

- Leber Congenital Amaurosis type 10 ("LCA10"), which is characterized by severe bilateral loss of vision at or soon after birth;
- STGD1; and
- IRDs associated with mutations in the USH2A gene, which include Usher syndrome type 2A, and USH2A-associated non-syndromic autosomal recessive retinitis pigmentosa.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the notes to the audited consolidated financial statements included in the Company's Annual Report on Form 10-K ("Annual Report") for the year ended December 31, 2022 filed with the Securities and Exchange Commission ("SEC") on March 1, 2023.

Basis of Presentation and Consolidation

In the opinion of management, the Company's condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair statement of the Company's financial statements for interim periods in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been

eliminated in consolidation. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's audited consolidated financial statements and the accompanying notes included in the Annual Report.

The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from the Company's audited financial statements but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

Segment and Geographic Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment.

Use of Estimates

The preparation of financial statements and related disclosures in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's Condensed Unaudited Consolidated Balance Sheets and the amount of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, accounting for research and development costs, accounting for share-based compensation and accounting for income taxes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less when purchased to be cash equivalents. The carrying amounts reported in the Condensed Unaudited Consolidated Balance Sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

Available for Sale Securities

The Company considers debt securities with original maturities of greater than 90 days to be available-for-sale securities. Available-for-sale securities with original maturities of greater than one year are recorded as non-current assets. Available-for -sale securities are recorded at fair value and unrealized gains and losses are recorded within other comprehensive income.

On a quarterly basis, the Company reviews the status of each security in an unrealized loss position, to evaluate the existence of potential credit losses. The Company first considers whether it intends to sell, or if it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through income. For securities that do not meet this criteria, the Company considers a number of factors to determine if the decline in fair value has resulted from credit losses or other factors, including but not limited to: (1) the extent of the decline; (2) changes to the rating of the security by a rating agency; (3) any adverse conditions specific to the security; and (4) other market conditions that may affect the fair value of the security. If this assessment indicates that a credit loss exists and the present value of cash flows expected to be collected is less than the amortized cost basis, an allowance for credit losses is required for the credit loss. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income.

Concentration of Suppliers

The Company historically relied upon a single third-party manufacturer to provide the drug substance for avacincaptad pegol on a purchase order basis. The Company also historically relied upon a single third-party manufacturer to provide fill/finish services for avacincaptad pegol drug product. The Company has engaged one additional third-party manufacturer to provide drug substance for avacincaptad pegol. The Company has also engaged a single third-party manufacturer to provide packaging services and the finished goods for avacincaptad pegol. In addition, the Company currently relies upon a single third-party supplier to supply on a purchase order basis the polyethylene glycol starting material used to manufacture avacincaptad pegol. Furthermore, the Company and its contract manufacturers currently rely upon sole-source suppliers of certain raw materials and other specialized components of production used in the manufacture and fill/finish of avacincaptad pegol. The Company currently relies upon a single third-party contract manufacturer to conduct process development, scale-up and current Good Manufacturing Practices ("cGMP") manufacture of the drug substance for IC-500 for preclinical toxicology studies and early-stage clinical trials and a single third-party contract manufacturer to conduct fill/finish services for IC-500. If the Company's third-party manufacturers or fill/finish service providers should become unavailable to the Company for any reason, including as a result of capacity constraints, different business objectives, financial difficulties, insolvency or the COVID-19

pandemic, the Company believes that there are a limited number of potential replacement manufacturers, and the Company likely would incur added costs and delays in identifying or qualifying such replacements.

Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes, as set forth in ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets when, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

Equity Investments

The Company holds investments in equity securities without a readily determinable fair value. Equity investments without a readily determinable fair value are recognized at fair value and are adjusted for observable price changes, or when qualitative assessments indicate that impairment exists, which is recorded in other income (loss).

Financial Instruments

Cash equivalents and available for sale securities are reflected in the accompanying financial statements at fair value. The carrying amount of accounts payable and accrued expenses, including accrued research and development expenses, approximates fair value due to the short-term nature of those instruments. The carrying amount of the Company's term loan approximates fair value due to the variable interest rate nature of the debt.

Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company reviews investments on a periodic basis for other than temporary impairments. This review is subjective as it requires management to evaluate whether an event or change in circumstances has occurred in the period that may have a significant adverse effect on the fair value of the investment. The Company uses the market approach to measure fair value for its financial assets. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets. The Company classifies its corporate debt securities within the fair value hierarchy as Level 2 assets, as it primarily utilizes quoted market prices or rates for similar instruments to value these securities.

The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market. The Company's Level 1 assets consist of investments in money market funds and U.S. Treasury securities.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability. The Company's Level 2 assets consist of investments in investment-grade corporate debt securities.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability. The Company does not hold any assets that are measured using Level 3 inputs.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents and available for sale securities.

The Company maintains its cash in bank accounts, the balances of which generally exceed federally insured limits. We monitor the credit ratings and our concentration of risk with these financial institutions on a continuing basis to safeguard our cash deposits. As more fully described below in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments", on July 26, 2022 (the "Closing Date"), the Company and certain of its subsidiaries (the "Subsidiary Borrowers") entered into a Loan and Security Agreement (the "Loan Agreement") with

Hercules Capital, Inc. (“Hercules”), in its capacity as administrative agent and collateral agent (in such capacity, the “Agent”) and as a lender, Silicon Valley Bank (“SVB”) and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders (collectively, the “Lenders”). The Loan Agreement contains a financial covenant requiring the Company and certain of the Subsidiary Borrowers, starting on the one (1) year anniversary of the Closing Date (July 26, 2023), to (i) maintain all of their respective operating accounts, depository accounts and excess cash in the United States with SVB or an SVB affiliate and (ii) obtain any business card, letter of credit and other material cash management services in the United States exclusively from SVB or an SVB affiliate.

The Company maintains its cash equivalents and available for sale securities in investments in money market funds, in U.S. Treasury securities, asset-backed securities and investment-grade corporate debt securities with original maturities of 90 days or less.

The Company believes it is not exposed to significant credit risk on its cash, cash equivalents and available for sale securities.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, it recognizes a right-of-use (“ROU”) asset and operating lease liability on the Company's Condensed Unaudited Consolidated Balance Sheet. ROU lease assets represent the Company's right to use the underlying asset for the lease term and the lease obligation represents the Company's commitment to make the lease payments arising from the lease. ROU lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As the Company’s leases do not provide an implicit discount rate, the Company has used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. ROU lease assets include any lease payments made prior to commencement and excludes any lease incentives. The lease term may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as common area costs and property taxes are expensed as incurred. For all office lease agreements the Company combines lease and nonlease components. Leases with an initial term of 12 months or less are not recorded on the Company's Condensed Unaudited Consolidated Balance Sheet.

Property and Equipment

Property and equipment, which consists mainly of clinical and laboratory equipment, computers, software, other office equipment, and leasehold improvements, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally three to ten years, using the straight-line method. Amortization of leasehold improvements is recorded over the shorter of the lease term or estimated useful life of the related asset.

Research and Development

The Company's research and development expenses primarily consist of costs associated with the manufacturing, development and preclinical and clinical testing of the Company’s product candidates and costs associated with its gene therapy research programs. The Company's research and development expenses consist of:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations (“CROs”) and contract development and manufacturing organizations (“CDMOs”) and other vendors for the production and analysis of drug substance and drug product; and
- employee-related expenses for employees dedicated to research and development activities, including salaries, benefits and share-based compensation expense.

Research and development expenses also include costs of acquired product licenses, in-process research and development, and related technology rights where there is no alternative future use, costs of prototypes used in research and development, consultant fees and amounts paid to collaborators.

All research and development expenses are charged to operations as incurred in accordance with ASC 730, *Research and Development*. The Company accounts for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes, as set forth in ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets when, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense.

Share-Based Compensation

The Company follows the provisions of ASC 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, consultants and non-employee directors, including employee stock options, restricted stock units ("RSUs") and options granted to employees to purchase shares under the 2016 Employee Stock Purchase Plan (the "ESPP"). Share-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is generally recognized as an expense over the requisite service period, net of estimated forfeitures. For grants containing performance-based vesting provisions, expense is recognized over the estimated achievement period only when the performance-based milestone is deemed probable of achievement. If performance-based milestones are later determined not to be probable of achievement, then all previously recorded stock-based compensation expense associated with such options will be reversed during the period in which the Company makes this determination.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

Stock Options

The Company estimates the fair value of stock options granted to employees, consultants, and non-employee directors on the date of grant using the Black-Scholes option-pricing model. The Company's computation of stock-price volatility is based on daily historical volatility during the time period that corresponds to the expected option term. The Company's computation of expected term is determined using the expected term of stock option grants to employees based on an analysis of actual option exercises. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends to stockholders and has no current intentions to pay cash dividends. The risk-free interest rate is based on the zero-coupon U.S. Treasury yield at the date of grant for a term equivalent to the expected term of the option.

The weighted-average assumptions used to estimate grant date fair value of stock options using the Black-Scholes option pricing model were as follows for the three month periods ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
Expected common stock price volatility	81%	101%
Risk-free interest rate	3.45%-4.22%	1.38%-1.63%
Expected term of options (years)	5.0	5.2
Expected dividend yield	—	—

RSUs

The Company estimates the fair value of RSUs granted to employees using the closing market price of the Company's common stock on the date of grant.

ESPP

In April 2016, the Company's board of directors adopted the ESPP pursuant to which the Company may sell up to an aggregate of 1,000,000 shares of its common stock. The ESPP was approved by the Company's stockholders in June 2016. The ESPP is considered compensatory and the fair value of the discount and look back provision are estimated using the Black-Scholes option-pricing model and recognized over the six month withholding period prior to purchase.

Recent Accounting Pronouncements

The Company has evaluated recent accounting pronouncements through the date the financial statements were issued and filed with the SEC and believes that there are none that will have a material impact on the Company's financial statements.

3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss by the weighted average common shares and pre-funded warrants outstanding during the period. Basic and diluted shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants as the exercise of such pre-funded warrants requires nominal consideration to be given for the delivery of the corresponding shares of common stock. As of March 31, 2023, the Company had no pre-funded warrants outstanding. For the periods when there is a net loss, shares underlying stock options and RSUs have been excluded from the calculation of diluted net loss per common share because the effect of including such shares would be anti-dilutive. Therefore, the weighted average common shares used to calculate both basic and diluted net loss per common share would be the same.

The following table sets forth the computation of basic and diluted net loss per common share for the periods indicated:

	Three Months Ended March 31,	
	2023	2022
Basic and diluted net loss per common share calculation:		
Net loss	$ (72,229)	$ (34,536)
Weighted average common shares outstanding - basic and dilutive	137,087	118,755
Net loss per share of common stock - basic and diluted	$ (0.53)	$ (0.29)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding for the periods presented, as the effect of including such shares would be anti-dilutive:

	Three Months Ended March 31,	
	2023	2022
Stock options outstanding	12,896,479	10,469,980
Restricted stock units	2,816,817	2,200,043
Total	15,713,296	12,670,023

4. Cash, Cash Equivalents and Available-for-Sale Securities

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at the date of purchase to be cash equivalents. As of March 31, 2023 and December 31, 2022, the Company had cash and cash equivalents of approximately $467.6 million and $476.3 million, respectively. Cash and cash equivalents included cash of $6.0 million at March 31, 2023 and $0.6 million at December 31, 2022. Cash and cash equivalents at March 31, 2023 and December 31, 2022 included $461.6 million and $475.7 million, respectively, of investments in money market funds.

The Company considers debt securities with original maturities of greater than 90 days at the date of purchase to be available for sale securities. As of March 31, 2023 and December 31, 2022, the Company held available for sale securities of $132.3 million and $170.5 million, respectively, all of which have maturities of less than one year.

The Company evaluates securities with unrealized losses, if any, to determine whether the decline in fair value has resulted from credit loss or other factors. The Company has determined that there were no credit losses in fair value of its investments as of March 31, 2023. Factors considered in determining whether a loss resulted from a credit loss or other factors included the length of time and extent to which the investment's fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, the extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security, and whether or not the Company will be required to sell the security before the recovery of its amortized cost.

The Company classifies these securities as available-for-sale. However, the Company has not sold and does not currently intend to sell its investments and the Company believes it is more likely than not that the Company will recover the carrying value of these investments.

The Company believes that its existing cash, cash equivalents and available-for-sale securities as of March 31, 2023 will be sufficient to fund its currently planned capital expenditure requirements and operating expenses for at least the next 12 months from the filing of this Quarterly Report on Form 10-Q.

Available for sale securities, including carrying value and estimated fair values, are summarized as follows:

	As of March 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 21,674	$ 1	$ (29)	$ 21,646
Corporate debt securities	86,102	—	(35)	86,067
U.S. government agency securities	9,761	7	—	9,768
Asset-backed securities	9,903	—	(33)	9,870
Supranational securities	5,008	—	(10)	4,998
Total	$ 132,448	$ 8	$ (107)	$ 132,349

	As of December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 27,481	$ 3	$ (61)	$ 27,423
Corporate debt securities	109,248	—	(119)	109,129
U.S. government agency securities	9,644	25	—	9,669
Asset-backed securities	19,360	—	(63)	19,297
Supranational securities	5,027	—	(14)	5,013
Total	$ 170,760	$ 28	$ (257)	$ 170,531

The Company's available for sale securities are reported at fair value on the Company's balance sheet. Unrealized gains (losses) are reported within other comprehensive income in the statements of comprehensive loss. The cost of securities sold and any realized gains/losses from the sale of available for sale securities are based on the specific identification method. The changes in accumulated other comprehensive income associated with the unrealized gain on available for sale securities during the three months ended March 31, 2023 and 2022, respectively, were as follows:

	Three months ended March 31,	
	2023	2022
Beginning balance	$ (229)	$ (90)
Current period changes in fair value before reclassifications, net of tax	130	(304)
Amounts reclassified from accumulated other comprehensive income, net of tax	—	—
Total other comprehensive loss	$ 130	$ (304)
Ending balance	$ (99)	$ (394)

5. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets

and liabilities that are measured at fair value on a recurring basis as of March 31, 2023:

	Fair Value Measurement Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 461,564	$ —	$ —
Investments in U.S. Treasury securities	$ 21,646	$ —	$ —
Investments in corporate debt securities	$ —	$ 86,067	$ —
Investments in U.S. government agency securities		9,768	
Investments in asset-backed securities	$ —	9,870	$ —
Investments in supranational securities	$ —	4,998	$ —

* Investments in money market funds are reflected in cash and cash equivalents in the accompanying Condensed Unaudited Consolidated Balance Sheets.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2022:

	Fair Value Measurement Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 475,689	$ —	$ —
Investments in U.S. Treasury securities	$ 27,423	$ —	$ —
Investments in corporate debt securities	$ —	$ 109,129	$ —
Investments in U.S. government agency securities	—	9,669	—
Investments in asset-backed securities	$ —	$ 19,297	$ —
Investments in supranational securities	$ —	$ 5,013	$ —

* Investments in money market funds are reflected in cash and cash equivalents in the accompanying Condensed Unaudited Consolidated Balance Sheets.

No transfer of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three months ended March 31, 2023.

6. Share-Based Compensation

Pursuant to the evergreen provisions of the Company's 2013 stock incentive plan (the “2013 Plan”), annual increases have resulted in the addition of an aggregate of approximately 18,166,000 additional shares to the 2013 Plan, including for 2023, an increase of approximately 2,542,000 shares. As of March 31, 2023, the Company had approximately 2,646,000 shares available for grant under the 2013 Plan.

In October 2019, the Company's board of directors adopted its 2019 Inducement Stock Incentive Plan (the “2019 Inducement Plan”) to reserve initially 1,000,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company as a material inducement to such individuals’ entry into employment with the Company within Rule 5635(c)(4) of the Nasdaq Listing Rules. The terms and conditions of the 2019 Inducement Plan are substantially similar to those of the 2013 Plan. In March 2020, February 2021, September 2021, December 2021, May 2022 and February 2023, the Company's board of directors amended the 2019 Inducement Plan to reserve an additional 1,000,000 shares, an additional 600,000 shares, an additional 1,000,000 shares, an additional 1,000,000 shares, an additional 1,000,000 shares and an additional 2,000,000 shares, respectively, of its common stock for issuance under the plan. As of March 31, 2023, the Company had approximately 1,995,000 shares available for grant under the 2019 Inducement Plan.

Share-based compensation expense, net of estimated forfeitures, includes expenses related to stock options and RSUs granted to employees, non-employee directors and consultants, as well as options granted to employees to purchase shares

under the ESPP. Stock-based compensation by award type was as follows:

	Three Months Ended March 31,	
	2023	2022
Stock options	$ 6,894	$ 3,323
Restricted stock units	4,838	2,005
Employee stock purchase plan	167	58
Total	$ 11,899	$ 5,386

The Company allocated stock-based compensation expense in the Company's Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 5,541	$ 2,661
General and administrative	6,358	2,725
Total	$ 11,899	$ 5,386

Stock Options

A summary of the stock option activity, weighted average exercise prices, options outstanding, exercisable and expected to vest as of March 31, 2023 is as follows (in thousands except weighted average exercise price):

	Number of Shares Underlying Options	Weighted Average Exercise Price
Outstanding, December 31, 2022	12,403	$ 14.70
Granted	784	$ 22.43
Exercised	(289)	$ 7.26
Forfeited	(1)	$ 8.64
Outstanding, March 31, 2023	12,897	$ 15.34
Vested and exercisable, March 31, 2023	5,668	$ 13.66
Vested and expected to vest, March 31, 2023	12,390	$ 15.28

As of March 31, 2023, there were approximately $72.5 million of unrecognized compensation costs, net of estimated forfeitures, related to stock option awards grants, which are expected to be recognized over a remaining weighted average period of 3.1 years.

RSUs

The following table presents a summary of the Company's outstanding RSU awards granted as of March 31, 2023 (in thousands except weighted average grant-date fair value):

	Restricted Stock Units	Weighted Average Grant-Date Fair Value
Outstanding, December 31, 2022	3,026	$ 15.12
Awarded	76	$ 22.71
Vested	(285)	$ 14.11
Forfeited	—	$ —
Outstanding, March 31, 2023	2,817	$ 15.43
Outstanding, expected to vest	2,624	$ 15.43

As of March 31, 2023, there were approximately $33.9 million of unrecognized compensation costs, net of estimated forfeitures, related to RSUs grants, which are expected to be recognized over a remaining weighted average period of 3.1 years.

ESPP

As of March 31, 2023, there were 676,853 shares available for future purchases under the ESPP. There were 35,541 and 15,095 shares issued under the ESPP during the three months ended March 31, 2023 and 2022, respectively. Cash proceeds from ESPP purchases were $532 thousand and $184 thousand during the three months ended March 31, 2023 and 2022, respectively.

7. Commitments and Contingencies

Avacincaptad Pegol - Archemix Corp.

The Company is party to an agreement with Archemix Corp. (“Archemix”) under which the Company in-licensed rights in certain patents, patent applications and other intellectual property related to avacincaptad pegol and pursuant to which the Company may be required to pay sublicense fees and make milestone payments (the “C5 License Agreement”). Under the C5 License Agreement, for each anti-C5 aptamer product that the Company may develop under the agreement, including avacincaptad pegol, the Company is obligated to make additional payments to Archemix of up to an aggregate of $50.5 million if the Company achieves specified development, clinical and regulatory milestones, with $24.5 million of such payments relating to a first indication, $23.5 million of such payments relating to second and third indications and $2.5 million of such payments relating to sustained delivery applications. Under the C5 License Agreement, the Company is also obligated to make additional payments to Archemix of up to an aggregate of $22.5 million if the Company achieves specified commercial milestones based on net product sales of all anti-C5 products licensed under the agreement. The Company is also obligated to pay Archemix a double-digit percentage of specified non-royalty payments the Company may receive from any sublicensee of its rights under the C5 License Agreement. The Company is not obligated to pay Archemix a running royalty based on net product sales in connection with the C5 License Agreement.

Avacincaptad Pegol Drug Substance - Agilent Technologies, Inc.

In March 2023, the Company entered into a Commercial Manufacturing and Supply Agreement with Agilent Technologies, Inc. ("Agilent"), relating to the commercial manufacturing and supply of avacincaptad pegol drug substance (the "Agilent Agreement"). Pursuant to the Agilent Agreement, Agilent has agreed to manufacture and supply to the Company, and the Company has agreed to purchase from Agilent, a specified percentage of its commercial requirements in the United States of the active pharmaceutical ingredient ("API") used in avacincaptad pegol. The Agilent Agreement has an initial term of seven years from the date of regulatory approval in the United States of the Company's NDA for avacincaptad pegol, followed by successive two-year automatic renewal periods, absent non-renewal or termination by either party in accordance with the terms of the Agilent Agreement. The Agilent Agreement provides for pricing for the API based on a per batch or per gram basis, depending on the scale for which the Company orders the API.

The Company may cancel any purchase order under the Agilent Agreement at any time, subject to the payment of specified cancellation fees. The Company may terminate the Agilent Agreement in the event that it cannot commercialize avacincaptad pegol due to regulatory or other medical, scientific or legal reasons. Agilent may terminate the Agilent Agreement in the event that the Company does not, over a specified period, purchase and take delivery of the agreed upon minimum requirements of API. Each party also has the right to terminate the Agilent Agreement for other customary reasons such as material breach and bankruptcy.

Avacincaptad Pegol Sustained Release Delivery Technology - DelSiTech

Under the DelSiTech License Agreement with DelSiTech, the Company is obligated to make payments up to an aggregate of €35.0 million, if the Company achieves specified clinical and development milestones with respect to a Licensed Product. In addition, the Company is also obligated to pay DelSiTech up to an aggregate of €60.0 million if the Company achieves specified commercial sales milestones with respect to worldwide net sales of the Licensed Product. The Company is also obligated to pay DelSiTech royalties at a low single-digit percentage of net sales of the Licensed Product. The royalties payable by the Company are subject to reduction under specified circumstances.

miniCEP290 Program - University of Massachusetts

Under its exclusive license agreement with the University of Massachusetts (“UMass”) for its miniCEP290 program, which targets LCA10, which is associated with mutations in the *CEP290* gene, the Company is obligated to pay UMass up to an aggregate of $14.75 million in cash and issue up to 75,000 shares of common stock of the Company if the Company achieves specified clinical and regulatory milestones with respect to a licensed product. In addition, the Company is obligated to pay UMass up to an aggregate of $48.0 million if the Company achieves specified commercial sales milestones with respect to a licensed product. The Company is also obligated to pay UMass royalties at a low single-digit percentage of net sales of licensed products. If the Company or any of its affiliates sublicenses any of the licensed patent rights or know-how to a third

party, the Company will be obligated to pay UMass a high single-digit to a mid-tens percentage of the consideration received in exchange for such sublicense, with the applicable percentage based upon the stage of development of the licensed products at the time the Company or the applicable affiliate enters into the sublicense. If the Company receives a priority review voucher from the FDA in connection with obtaining marketing approval for a licensed product, and the Company subsequently uses such priority review voucher in connection with a different product candidate outside the scope of the agreement, the Company will be obligated to pay UMass a low-tens percentage of the fair market value of the priority review voucher at the time of approval of such product candidate and a low-twenties percentage of the fair market value of the priority review voucher at the time of achievement of a specified commercial sales milestone for such product candidate. In addition, if the Company sells such a priority review voucher to a third party, the Company will be obligated to pay UMass a low-thirties percentage of any consideration received from such third party in connection with such sale.

IC-500 - Former Equityholders of Inception 4

Under the agreement and plan of merger between the Company and Inception 4, Inc. (“Inception 4”), pursuant to which the Company acquired IC-500 and its other HtrA1 inhibitors (the “Inception 4 Merger Agreement”), the Company is obligated to make payments to the former equityholders of Inception 4 of up to an aggregate of $105 million, subject to the terms and conditions of the Inception 4 Merger Agreement, if the Company achieves certain specified clinical and regulatory milestones with respect to IC-500 or any other product candidate from its HtrA1 inhibitor program, with $45 million of such potential payments relating to GA and $60 million of such potential payments relating to wet AMD. Under the Inception 4 Merger Agreement, the Company does not owe any commercial milestones or royalties based on net sales. The future milestone payments will be payable in the form of shares of the Company's common stock, calculated based on the price of its common stock over a five-trading day period preceding the achievement of the relevant milestone, unless and until the issuance of such shares would, together with all other shares issued in connection with the acquisition, exceed an overall maximum limit of approximately 7.2 million shares, which is equal to 19.9% of the number of issued and outstanding shares of the Company's common stock as of the close of business on the business day prior to the closing date of the Inception 4 acquisition, and will be payable in cash thereafter. The Inception 4 Merger Agreement also includes customary indemnification obligations to the former equityholders of Inception 4, including for breaches of the representations and warranties, covenants and agreements of the Company and its subsidiaries (other than Inception 4) in the Inception 4 Merger Agreement.

Employment Contracts

The Company also has letter agreements with certain employees that require the funding of a specific level of payments if certain events, such as a termination of employment by the employee for good reason or by the Company without cause, in each case in connection with a change of control, occur.

Contract Service Providers

In addition, in the course of normal business operations, the Company has agreements with contract service providers to assist in the performance of the Company’s research and development, manufacturing and commercial planning activities. Expenditures to CROs, CDMOs and other service providers represent significant costs in preclinical and clinical development and commercial planning. Subject to required notice periods and the Company’s obligations under binding purchase orders and any cancellation fees that the Company may be obligated to pay, the Company can elect to discontinue the work under these agreements at any time.

8. Operating Leases

The Company leases office space located in Cranbury, New Jersey and Parsippany, New Jersey under non-cancelable operating lease arrangements. During May 2022, the Company amended its Cranbury office space lease to extend the lease period by one year through the end of February 2024. During June 2022, the Company amended its Parsippany office lease to include an additional portion of the premises consisting of approximately 34,836 square feet of the third floor of the building. The Parsippany lease expires at the end of August 2023.

As of June 30, 2022, the Company recognized additional right-of-use assets and lease liabilities of approximately $1.0 million, which represents the present value of its remaining lease payments using a weighted average estimated incremental borrowing rate of 8%.

For the three months ended March 31, 2023 and 2022, lease expense was $0.4 million and $0.3 million, respectively. Cash paid from operating cash flows for amounts included in the measurement of lease liabilities was $0.4 million and $0.3 million, for the three months ended March 31, 2023 and 2022, respectively. At March 31, 2023, the Company's operating leases had a weighted average remaining lease term of 0.5 years and a weighted average estimated incremental borrowing rate of 5.6%.

The following presents the maturity of the Company's operating lease liabilities as of March 31, 2023:

Remainder of 2023	775
2024	11
Total remaining obligation	786
Less imputed interest	(12)
Present value of lease liabilities	774

9. Loan and Security Agreement

On July 26, 2022 (the "Closing Date"), the Company and the Subsidiary Borrowers entered into the Loan Agreement with Hercules, in its capacity as Agent and as a lender, SVB and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders. The Loan Agreement provides for term loans in an aggregate principal amount of up to $250.0 million under multiple tranches (the "2022 Term Loan Facility"), available as follows: (i) a term loan advance in the amount of $50.0 million, which was drawn on the Closing Date; (ii) subject to the Company's announcement that the GATHER2 trial evaluating avacincaptad pegol in GA has achieved its protocol-specified primary endpoint and the Company has a sufficient clinical data package to support the submission of an NDA to the FDA for avacincaptad pegol in GA ("Milestone 1"), a second tranche consisting of term loan advances in the aggregate principal amount of $50.0 million available at the Company's option beginning on the date that Milestone 1 is achieved through December 15, 2022, which was drawn in December 2022; (iii) subject to the Company's submission of an NDA to the FDA for avacincaptad pegol in GA and the FDA accepting such NDA for review ("Milestone 2"), a third tranche consisting of term loan advances in the aggregate principal amount of $25.0 million, available at the Company's option beginning on the date that Milestone 2 is achieved through September 30, 2023; (iv) subject to FDA approval of avacincaptad pegol in GA with a label generally consistent with that sought in the Company's NDA ("Milestone 3"), a fourth tranche consisting of term loan advances in the aggregate principal amount of $75.0 million, available at the Company's option beginning on the date that Milestone 3 is achieved and continuing through the earlier of (x) September 30, 2024 and (y) the date that is 90 days after the date that Milestone 3 is achieved; and (v) subject to approval by the Lenders' investment committee in its discretion, a fifth tranche of additional term loans in an aggregate principal amount of up to $50.0 million, available on or before the Amortization Date (as defined below). The Company believes it has achieved Milestone 2 and plans to borrow the full $25.0 million tranche that is available during 2023. With the exception of the first and second $50.0 million tranches drawn on the Closing Date and in December 2022, respectively, each of the tranches may be drawn down in $5.0 million increments at the Company's election upon achievement of the relevant milestones specified in the Loan Agreement. The Company has agreed to use the proceeds of the 2022 Term Loan Facility for working capital and general corporate purposes.

Notwithstanding limitations and restrictions imposed by covenants in the Loan Agreement, the Company is permitted to engage in certain specified transactions. For example, the terms of the Loan Agreement provide that the Company may issue convertible notes in an aggregate principal amount of not more than $400.0 million, provided that such notes are unsecured, have a maturity date no earlier than six months following the Maturity Date (as defined below), and meet certain other conditions. The Loan Agreement also provides that the Company may enter into royalty interest financing transactions that are subordinated to the 2022 Term Loan Facility, have a maturity date no earlier than six months following the Maturity Date, and meet certain other conditions. Following the achievement of Milestone 3, the Loan Agreement also provides for a possible additional revolving credit facility of up to $50.0 million, which will be formula-based and backed by the Company's accounts receivables. This potential revolving credit facility is not an existing facility under the Loan Agreement, is not committed, and is subject to agreement among the Company and the Lenders. The Company may enter into non-exclusive and certain specified exclusive licensing arrangements with respect to core intellectual property and non-exclusive and exclusive licensing arrangements or otherwise transfer non-core intellectual property without the consent of the Lenders. The Company may also enter into certain permitted acquisitions, subject to a limit on total cash consideration for acquisitions consummated during specified periods. Additionally, the Company must provide the Lenders the opportunity to invest up to $10.0 million in any equity financing, subject to certain exclusions, that is broadly marketed to multiple investors and in which the Company receives net cash proceeds of $75.0 million or more in any one or series of related financings (or in the case of any such equity financing that is a registered offering, use its commercially reasonable efforts to provide such opportunity to the Lenders).

The 2022 Term Loan Facility will mature on August 1, 2027 (the "Maturity Date"). The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) (x) the lesser of the Wall Street Journal prime rate and 6.25% plus (y) 4.00% or (ii) 8.75%. The per annum interest rate is capped at 10.25%. Accrued interest is payable monthly following the funding of each term loan. The Company may make payments of interest only, without any loan amortization payments, for a period of 42 months following the Closing Date, which period may be

extended to the Maturity Date if (i) Milestone 3 has been achieved and (ii) no default or event of default exists under the Loan Agreement. At the end of the interest only period (the "Amortization Date"), the Company is required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly installments.

As collateral for the obligations under the 2022 Term Loan Facility, the Company has granted to the Agent for the benefit of the Lenders a senior security interest in substantially all of its and each Subsidiary Borrower's property, inclusive of intellectual property, with certain limited exceptions set forth in the Loan Agreement.

The Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent (the "Qualified Cash") during the period commencing on May 15, 2023 through August 14, 2024. Effective as of July 26, 2023, the Company and certain of the Subsidiary Borrowers will be required to (i) maintain all of their respective operating accounts, depository accounts and excess cash in the United States with SVB or an SVB affiliate and (ii) obtain any business card, letter of credit and other material cash management services in the United States exclusively from SVB or an SVB affiliate. Commencing on August 15, 2024, the Company will also be required to maintain a certain minimum amount of trailing six-month net product revenue from the sale of avacincaptad pegol, tested on a quarterly basis. The revenue covenant will be waived at any time at which the Company (x) (i) maintains a market capitalization in excess of $600.0 million and (ii) maintains Qualified Cash in an amount greater than or equal to 50% of the outstanding 2022 Term Loan Facility at such time or (y) maintains Qualified Cash in an amount greater than or equal to 90% of the outstanding 2022 Term Loan Facility at such time. Upon the occurrence of an event of default, including a material adverse effect, subject to certain exceptions, on the business, operations, properties, assets or financial condition of the Company and the Subsidiary Borrowers taken as a whole, and subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by the Lenders. As of March 31, 2023, the Company was in compliance with all applicable covenants under the Loan Agreement.

In addition, the Company is required to make a final payment fee (the "End of Term Charge") upon the earlier of (i) the Maturity Date or (ii) the date the Company prepays, in full or in part, the outstanding principal balance of the 2022 Term Loan Facility. The End of Term Charge is 4.25% of the aggregate original principal amount of the term loans repaid or prepaid under the Loan Agreement.

The Company may, at its option, prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.0% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the Closing Date, (ii) 1.5% of the principal amount prepaid if the prepayment occurs on or after the first anniversary and prior to the second anniversary of the Closing Date, and (iii) 0.75% of the principal amount prepaid if the prepayment occurs on or after the second anniversary and prior to the third anniversary of the Closing Date.

During the three months ended March 31, 2023, the Company recognized interest expense on its Consolidated Statements of Operations and Comprehensive Loss in connection with the 2022 Term Loan Facility as follows:

	Three months ended March 31, 2023
Interest expense for 2022 Term Loan Facility	$ 2,563
Accretion of end of term charge	220
Amortization of debt issuance costs	199
Total interest expense related to 2022 Term Loan Facility	$ 2,982

The principal balance of the 2022 Term Loan Facility and related accretion and amortization as of March 31, 2023, were as follows:

	March 31, 2023
2022 Term Loan Facility, gross (amount drawn)	$ 100,000
Debt issuance costs (legal and other administrative fees)	(3,898)
Accretion of end of term charge	435
Accumulated amortization of debt issuance costs	450
2022 Term Loan Facility, net	$ 96,987

10. Subsequent Events

Sale of New Jersey Net Operating Losses

During April 2023, through the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program"), the Company received $11.8 million as it completed the sale of approximately $139.3 million of its New Jersey State net operating losses ("NOLs"). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits, subject to a maximum lifetime benefit of $20.0 million. Under the Program, if the Company fails to use the net proceeds received from the Program for allowable expenditures or fails to maintain a headquarters or a base of operations in New Jersey during the five years following the closing date, the Company may be subject to the recapture of up to the face value of the tax benefits.

Merger Agreement

On April 28, 2023, the Company and Astellas entered into the Merger Agreement, pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving the Merger as a wholly owned subsidiary of Astellas.

At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.001 per share, of the Company issued and outstanding as of immediately prior to the Effective Time (other than Excluded Shares (as defined in the Merger Agreement) and Dissenting Shares (as defined in the Merger Agreement)) will be cancelled and automatically converted into the right to receive cash in an amount equal to $40.00, without interest (the "Merger Consideration") and subject to any withholding of taxes. The Merger Agreement requires Guarantor to guarantee the covenants, obligations (including payment obligations) and liabilities applicable to Astellas, Merger Sub or the surviving corporation, as applicable, under the Merger Agreement.

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal impediments, no material adverse effect having occurred since the signing of the Merger Agreement, the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other antitrust authority specified in the Merger Agreement, solely to the extent the approval of any such authority is required in connection with the Merger, and approval by the Company's stockholders. The Company expects the Merger and the other transactions contemplated by the Merger Agreement to close in the third calendar quarter of 2023.

The Company has made customary representations and warranties in the Merger Agreement and has agreed to customary covenants regarding the operation of the business of the Company and its subsidiaries prior to the Effective Time. The Company is also subject to customary restrictions on its ability to solicit alternative acquisition proposals from third parties and to provide non-public information to, and participate in discussions and engage in negotiations with, third parties regarding alternative acquisition proposals, with customary exceptions to allow the board of directors of the Company to exercise its fiduciary duties.

The Merger Agreement contains certain termination rights for the Company and Astellas. Subject to certain limitations, the Company or Astellas may terminate the Merger Agreement if the Merger is not consummated by midnight Eastern Time, on October 27, 2023, subject to an automatic 90-day extension in the event that all conditions other than the required antitrust approvals have been obtained or waived as of such date and a second automatic 90-day extension thereafter in the event that all conditions other than the required antitrust approvals have been obtained or waived as of such extended date (the "End Date").

Upon termination of the Merger Agreement, under specified circumstances, the Company will be required to pay Astellas a termination fee of approximately $222.4 million. Such circumstances include where the Merger Agreement is terminated (i) in connection with the Company accepting a Superior Offer (as defined in the Merger Agreement) approved by the Company's board of directors, (ii) due to the Company's board of directors' change or withdrawal of, or failure to reaffirm, its recommendation of the Merger, or (iii) because the Company's board of directors or the Company intentionally breach their non-solicit obligations under the Merger Agreement in any material respects. This termination fee will also be payable if the Merger Agreement is terminated because the Company's stockholders did not vote to adopt the Merger Agreement, the Merger is not consummated before the End Date, or the Company breaches its representations, warranties or covenants in a manner that would cause the related closing conditions to not be met, and prior to any such termination, a proposal to acquire at least 50% of the Company's stock or assets is communicated to the Company's board of directors or publicly disclosed and within one year after the termination of the Merger Agreement the Company enters into an agreement for, or consummates, such a transaction, whether or not the consummated transaction was the one contemplated by such proposal.

At the Effective Time, each option to purchase shares of the Company (each, a "Company Option") that is then outstanding and unexercised, whether or not vested and which has a per share exercise price that is less than the Merger Consideration (each, an "In the Money Option"), will be cancelled and converted into the right to receive a cash payment equal to (A) the excess of (x) the Merger Consideration over (y) the exercise price payable per share under such In the Money Option, multiplied by (B) the total number of shares subject to such In the Money Option immediately prior to the Effective Time (without regard to vesting). In addition, at the Effective Time, each Company Option other than an In the Money Option that is then outstanding and unexercised, whether or not vested, will be cancelled with no consideration payable in respect thereof. At the Effective Time, each then outstanding restricted stock unit with respect to shares of the Company (each, a "Company RSU") will be canceled and the holder thereof will be entitled to receive a cash payment equal to the product of (x) the Merger Consideration and (y) the number of shares subject to such Company RSU. At the Effective Time, each then outstanding performance vesting restricted stock unit with respect to shares of the Company (each, a "Company PSU") will be canceled and converted into a cash-based award, which will entitle the holder thereof to receive a cash payment equal to the product of (x) the Merger Consideration, and (y) the number of shares subject to such Company PSU, subject to the same terms and conditions (including vesting, forfeiture and acceleration provisions) that were applicable to the corresponding Company PSU immediately prior to the Effective Time.

The representations, warranties and covenants of the Company contained in the Merger Agreement have been made solely for the benefit of Astellas and Merger Sub. In addition, such representations, warranties and covenants (i) have been made only for purposes of the Merger Agreement, (ii) have been qualified by (a) subject to certain terms and conditions, matters specifically disclosed in the Company's filings with the SEC prior to the date of the Merger Agreement and (b) confidential disclosures made to Astellas and Merger Sub in the disclosure letter delivered in connection with the Merger Agreement, (iii) are subject to materiality qualifications contained in the Merger Agreement which may differ from what may be viewed as material by investors, and (iv) have been included in the Merger Agreement for the purpose of allocating risk between the contracting parties rather than establishing matters as fact.

If the Merger is completed, the Company expects that its common stock will thereafter be removed from listing on the Nasdaq Global Select Market and from registration under Section 12(b) of the Securities Exchange Act of 1934, as amended, and the Company will cease to be a publicly traded company.

Bylaws Amendment

On April 28, 2023, the board of directors of the Company approved an amendment to the Company's existing Amended and Restated Bylaws (the "Bylaws") to add a new Article V, Section 9 forum selection provision (the "Forum Selection Amendment").

The Forum Selection Amendment provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company; (ii) any action asserting a claim of breach of a duty (including any fiduciary duty) owed by any current or former director, officer, stockholder, employee or agent of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim against the Company or any current or former director, officer, stockholder, employee or agent of the Company arising out of or relating to any provision of the General Corporation Law of the State of Delaware, the Certificate of Incorporation of the Company or the Bylaws (each, as in effect from time to time), or (iv) any action asserting a claim against the Company or any current or former director, officer, stockholder, employee or agent of the Company governed by the internal affairs doctrine of the State of Delaware; provided, however, that, in the event that the Court of Chancery of the State of Delaware lacks subject matter jurisdiction over any such action or proceeding, the sole and exclusive forum for such action or proceeding will be another state or federal court located within the State of Delaware, in each such case, unless the Court of Chancery (or such other state or federal court located within the State of Delaware, as applicable) has dismissed a prior action by the same plaintiff asserting the same claims because such court lacked personal jurisdiction over an indispensable party named as a defendant therein.

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

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and certainty of cash flows from operations and from outside sources, so as to allow investors to better view our company from management's perspective. This discussion and analysis should be read together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 1, 2023, and elsewhere in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Merger Agreement

On April 28, 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Astellas US Holdings, Inc., a Delaware corporation, or Astellas, Berry Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Astellas, or Merger Sub, and solely as provided by Section 8.10(b) of the Merger Agreement, Astellas Pharma Inc., a company organized under the laws of Japan, or the Guarantor, pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into our company, or the Merger, with our company surviving the Merger as a wholly owned subsidiary of Astellas. On the terms and subject to the conditions set forth in the Merger Agreement, at the effective time of the Merger, each share of our common stock, par value $0.001 per share, that is issued and outstanding as of immediately prior to the effective time of the Merger (other than Excluded Shares (as defined in the Merger Agreement) and Dissenting Shares (as defined in the Merger Agreement)) will be cancelled and automatically converted into the right to receive cash in an amount equal to $40.00, without interest, and subject to any withholding of taxes. The Merger Agreement requires Guarantor to guarantee the covenants, obligations (including payment obligations) and liabilities applicable to Astellas, Merger Sub or the surviving corporation, as applicable, under the Merger Agreement.

The Merger Agreement contains certain termination rights for us and Astellas. If the Merger Agreement is terminated under specified circumstances, we will be required to pay Astellas a termination fee of approximately $222.4 million.

Although we anticipate closing the Merger in the third calendar quarter of 2023, the closing of the Merger is subject to customary closing conditions, and we may not complete the pending Merger with Astellas within the timeframe we anticipate, or at all. If the Merger is completed, we expect that our common stock will thereafter be removed from listing on the Nasdaq Global Select Market and from registration under Section 12(b) of the Securities Exchange Act of 1934, as amended, and we will cease to be a publicly traded company. However, except as otherwise indicated, we have prepared this Quarterly Report on Form 10-Q and the forward-looking statements contained in this Quarterly Report as if we were going to remain an independent, standalone company. If the Merger is consummated, many of the forward-looking statements contained in this Quarterly Report on Form 10-Q would no longer be applicable.

For further discussion, refer to "Note 10-Subsequent Events", in the notes to the financial statements filed with this Quarterly Report on Form 10-Q. In addition, please refer to "Item 1A. Risk Factors – Risks Related to our Pending Merger with Astellas" in Part II, Item 1A. of this Quarterly Report on Form 10-Q for a discussion of the relevant risks regarding the pending Merger with Astellas.

Overview

We are a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. We are committed to having a positive impact on patients' lives by delivering high-quality, safe and effective treatments designed to address debilitating retinal diseases, including earlier stages of age-related macular degeneration, or AMD.

Our lead asset is our clinical stage product candidate avacincaptad pegol, which is also referred to as ACP, a complement C5 inhibitor. We are currently targeting the following diseases with ACP:

- Geographic Atrophy, or GA, which is the advanced stage of AMD and is characterized by marked thinning or atrophy of retinal tissue, leading to irreversible loss of vision;

- intermediate AMD, which is an earlier stage of AMD; and
- autosomal recessive Stargardt disease, or STGD1, which is an orphan inherited condition characterized by progressive damage to the central portion of the retina, or the macula, and other retinal tissue, leading to loss of vision.

In October 2019, we announced positive 12-month data for GATHER1, our first Phase 3 clinical trial evaluating ACP for the treatment of GA secondary to AMD. In GATHER1, 286 patients were randomized to receive various doses of ACP, including ACP 2 mg, or sham control. We observed a 27.7% (p-value = 0.0063) reduction in the mean rate of growth (slope) estimated based on GA area between the ACP 2 mg group and the corresponding sham control group over 12 months, when performing the primary analysis, and a 35.4% (p-value = 0.0050) reduction in the mean rate of growth (slope) estimated based on GA area between the two groups over 12 months, when performing the supportive analysis. These results are based on an analysis of the primary efficacy endpoint required by the U.S. Food and Drug Administration, or FDA, in accordance with our Special Protocol Assessment, or the SPA, which we describe further below. We analyzed the endpoint by using the square root transformation of the GA area, which we refer to as the primary analysis, and we analyzed the endpoint by using the observed GA area (without square root transformation), which we refer to as the supportive analysis. In GATHER1, through month 12, we did not observe any events of endophthalmitis or ischemic optic neuropathy events, and only one case of intraocular inflammation, which was mild and transient and reported as related to the injection procedure. The incidence of choroidal neovascularization, or CNV, in the study eye through month 12 was 6 patients (9.0%) in the ACP 2 mg group and 3 patients (2.7%) in the corresponding sham control group.

In June 2020, we started enrolling patients in GATHER2, our second Phase 3 clinical trial evaluating ACP for the treatment of GA secondary to AMD. In July 2021, we received a written agreement from the FDA under the SPA for the overall design of GATHER2. The SPA is a procedure by which the FDA provides a clinical trial sponsor with an official evaluation and written guidance on the design of a proposed protocol intended to form the basis for a new drug application, or NDA. In connection with our SPA, the FDA recommended, and we accepted, modifying the primary efficacy endpoint for the GATHER2 trial from the mean rate of change in GA area over 12 months measured by fundus autofluorescence, or FAF, at three timepoints: baseline, month 6 and month 12, to the mean rate of growth (slope) estimated based on GA area measured by FAF in at least three timepoints: baseline, month 6 and month 12.

In September 2022, we announced positive 12-month top-line data for GATHER2. In GATHER2, 448 patients were randomized on a 1:1 basis to receive ACP 2 mg or sham control over the first 12 months of the trial. At 12 months, we measured the primary efficacy endpoint in accordance with the SPA. In GATHER2, we observed a 14.3% (p-value = 0.0064) reduction in the mean rate of growth (slope) in GA area between the two groups at 12 months with the primary analysis, and a 17.7% (p-value = 0.0039) reduction in the mean rate of growth (slope) in GA area between the two groups at 12 months with the supportive analysis. We did not observe any events of endophthalmitis, intraocular inflammation events, events of vasculitis or ischemic optic neuropathy events through month 12, and the incidence of CNV in the study eye through month 12 was 15 patients (6.7%) in the ACP 2 mg group and 9 patients (4.1%) in the sham control group.

In March 2023, we announced results from an exploratory time-to-event analysis from the GATHER1 and GATHER2 clinical trials evaluating reduction in vision loss with ACP 2 mg versus sham treatment. The GATHER1 and GATHER2 clinical trials were designed to evaluate the rate of GA lesion growth in patients with GA secondary to AMD. The post-hoc analysis for vision loss from these pivotal trials signals up to a 59% reduction in rate of vision loss with ACP 2 mg compared to sham treatment at 12 months. The results were consistent in the GATHER1 and GATHER2 clinical trials independently, signaling a 44% reduction (Hazard Ratio 0.56 with 95% CI, 0.15-2.06) and a 59% percent reduction (Hazard Ratio 0.41 with 95% CI, 0.17-1.00) respectively in the rate of vision loss with ACP 2 mg compared to sham over the first 12 months of treatment. In a combined analysis of GATHER1 and GATHER2, patients treated with ACP 2 mg experienced a 56% reduction (Hazard Ratio 0.44, with 95% CI, 0.21-0.92) in the rate of vision loss compared to sham over the first 12 months of treatment. Vision loss in this analysis was defined as a loss of ≥15 letters (EDTRS) in best corrected visual acuity, or BCVA, from baseline measured at any two consecutive visits up to month 12.

We believe that with the statistically significant results from our GATHER1 and GATHER2 trials and the safety profile of ACP to date, we have sufficient data from two independent, adequate and well-controlled pivotal clinical trials of ACP in GA secondary to AMD to support an application for marketing approval. In November 2022, the FDA granted breakthrough therapy designation to ACP for the treatment of GA secondary to AMD. In December 2022, we completed the rolling submission of our NDA to the FDA for marketing approval of ACP for the treatment of GA secondary to AMD. In February 2023, the FDA accepted our NDA for filing and granted priority review with a Prescription Drug User Fee Act, or PDUFA, target action date of August 19, 2023.

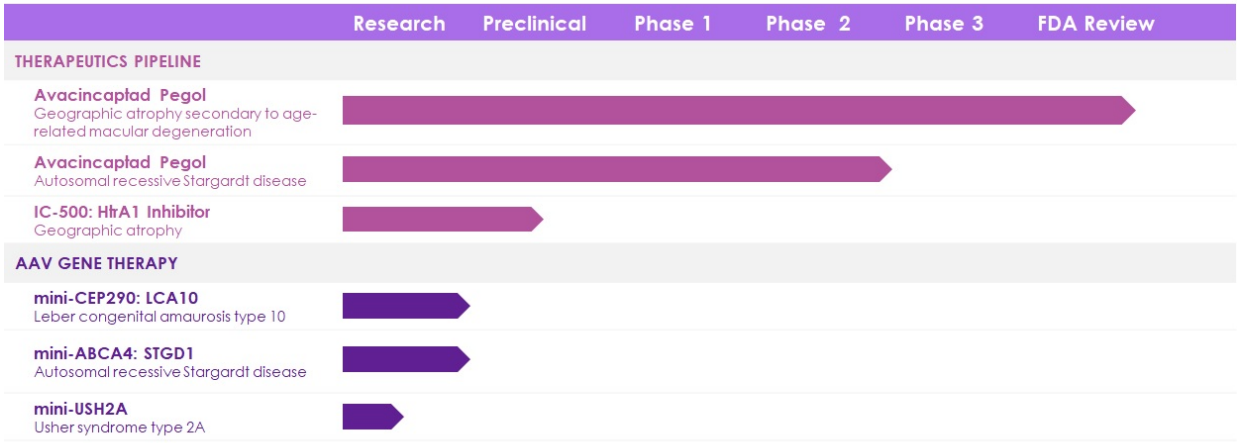
In addition to ACP, we are developing our preclinical product candidate IC-500, a High temperature requirement A serine peptidase 1 protein, or HtrA1, inhibitor, for GA secondary to AMD and potentially other age-related retinal diseases.

Our portfolio also includes several ongoing gene therapy research programs, each of which uses adeno-associated virus, or AAV, for gene delivery. These AAV mediated gene therapy programs are targeting the following orphan inherited retinal diseases, or IRDs:

- Leber Congenital Amaurosis type 10, or LCA10, which is characterized by severe bilateral loss of vision at or soon after birth;
- STGD1; and
- IRDs associated with mutations in the USH2A gene, which include Usher syndrome type 2A, or Usher 2A, and USH2A-associated non-syndromic autosomal recessive retinitis pigmentosa.

Research and Development Pipeline

We have summarized the current status of our ongoing research and development programs in the table below.



Therapeutic Development Programs

Avacincaptad Pegol

Avacincaptad pegol, our complement C5 inhibitor, is a chemically-synthesized, pegylated RNA aptamer. Aptamers are short molecules made up of a single stranded nucleic acid sequence or amino acid sequence that binds molecular targets with high selectivity and specificity. The following are brief descriptions of the regulatory status, commercial planning, manufacturing activities, clinical trials and lifecycle management activities for ACP.

Avacincaptad pegol Regulatory Status

Our NDA for marketing approval of ACP for the treatment of GA secondary to AMD is currently under review by the FDA, with a PDUFA target action date of August 19, 2023. In April 2023, we had a mid-review cycle meeting with the FDA, during which the FDA communicated that no significant issues had been identified in our NDA at that time.

In April 2023, we had a joint rapporteur and co-rapporteur pre-submission meeting to discuss and obtain feedback on the overall content and format of our planned marketing authorization application, or MAA, to the European Medicines Agency, or EMA. We believe the discussions at this meeting support our regulatory strategy for seeking marketing approval from the EMA for ACP for the treatment of GA secondary to AMD. We are also planning for a similar interaction with the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom. We are planning to submit MAAs to the EMA and the MHRA during the third quarter of 2023.

Commercial Preparation Activities

We are continuing to build our commercial capabilities and infrastructure in anticipation of a potential launch of ACP in the United States for GA, if approved. In April 2023, we completed the hiring of a majority of our field based sales force, and we expect to complete the hiring of the remainder of our sales force before potential launch. In addition, we are continuing to hire additional personnel across core areas such as marketing, patient access and reimbursement, analytics and operations, and

product distribution. We are continuing to build internal and external infrastructure to support our planned commercialization efforts.

Avacincaptad Pegol Manufacturing

We are working with our historical contract manufacturer for avacincaptad pegol drug substance, Agilent Technologies, Inc., or Agilent, to scale up and potentially validate the manufacturing process for avacincaptad pegol drug substance. In 2022, Agilent completed the manufacture of multiple batches of avacincaptad pegol drug substance at a larger scale, a scale which we believe can support commercial launch, if approved. In March 2023, we entered into an agreement with Agilent for long-term commercial manufacture and supply of ACP drug substance. We are continuing to work with Agilent on additional scale up and validation activities.

In parallel, we are working with a new contract manufacturer with the goal of assessing whether this manufacturer can produce ACP drug substance at an adequate scale for potential commercial use. Subject to successful completion of scale up and validation activities, we currently plan to use Agilent as the primary source of supply of ACP drug substance upon launch, if approved, and the new manufacturer as a second source of supply of ACP drug substance.

We are working with our historical fill/finish manufacturer, Ajinomoto Bio-Pharma Services, or Ajinomoto, on fill/finish of avacincaptad pegol drug product. We believe Ajinomoto has the capacity to supply us with avacincaptad pegol drug product for our expected commercial supply needs upon launch, if approved. We are continuing discussions with Ajinomoto for long-term supply of ACP drug product and are assessing additional suppliers of ACP drug product.

We order the polyethylene glycol, or PEG, starting material used to make avacincaptad pegol drug substance from a sole source third-party manufacturer outside the United States. We currently procure the supply on a purchase order basis and are continuing discussions regarding a long-term supply agreement with this manufacturer for the PEG starting material. We believe this supplier has the capacity to supply us with the PEG at the scale that we will need for commercial manufacturing.

We have also engaged a third-party manufacturer to package ACP drug product to produce finished goods for potential commercial distribution.

ACP Clinical Trials

The following are brief summaries of the status of our ongoing clinical trials for ACP.

GATHER2 (GA secondary to AMD)

GATHER2 is an international, randomized, double-masked, sham controlled, multi-center Phase 3 clinical trial evaluating the safety and efficacy of avacincaptad pegol for the treatment of GA secondary to AMD. 448 patients were enrolled in this trial. In September 2022, we announced 12-month top-line data from this trial. We plan to treat and follow patients for 24 months in total.

ISEE2009 Open-Label Extension Study

We initiated an open-label extension study, or the OLE study, which is an international, open-label, multi-center clinical trial assessing the safety of intravitreal administration of avacincaptad pegol in patients who completed their month 24 visits in the GATHER2 trial. All patients participating in the OLE study will receive monthly doses of avacincaptad pegol 2 mg, regardless of the treatment arm (avacincaptad pegol or sham procedure) that they were randomized to in GATHER2. We are continuing to enroll patients and plan to treat and follow patients for up to 18 months or until marketing approval of avacincaptad pegol in the applicable region, whichever is sooner.

STAR (STGD1)

STAR is an international, randomized, double-masked, sham controlled, multi-center clinical trial evaluating the safety and efficacy of avacincaptad pegol for the treatment of STGD1. We initially enrolled 95 patients in the STAR trial, none of whom have any remaining study visits. We continue to enroll new patients in the United States and plan to enroll approximately 25 additional patients, with the goal of enrolling a total of approximately 120 patients. Newly enrolled patients are randomized on a 1:1 basis to be treated with either avacincaptad pegol 4 mg or sham for 18 months. We have been and plan to remain masked to the treatment group of all patients in the trial. In addition, we have not reviewed and do not plan to review or analyze efficacy data for any patients in the trial, until the 18-month data has been collected and analyzed for all patients enrolled in the trial.

Avacincaptad Pegol Lifecycle Initiatives

We continue to pursue multiple sustained release delivery technologies for avacincaptad pegol, including conducting feasibility studies of avacincaptad pegol with those technologies and analyzing and evaluating the resulting formulations. One of the technologies is DelSiTech's proprietary silica-based sustained release technology, with which we are continuing formulation and other studies. In addition to DelSiTech's technology, we continue to evaluate other sustained release delivery technologies for avacincaptad pegol. If any of the other resulting formulations are promising, we may pursue long-term development collaborations with those technologies.

Gene Therapy Research and Development Programs

Minigene Programs

The following is a summary of our minigene programs and their status:

- **miniCEP290 (LCA10):** This program, which we refer to as the miniCEP290 program, is targeting LCA10, which is associated with mutations in the *CEP290* gene. In July 2019, we entered into a license agreement with the University of Massachusetts, or UMass, for exclusive development and commercialization rights to this program. We have identified a lead construct from this program and are considering preclinical development options.

- **miniABCA4 (STGD1):** This program, which we refer to as the miniABCA4 program, is targeting STGD1, which is associated with mutations in the *ABCA4* gene. We have identified a lead construct from this program and are considering preclinical development options. We are discussing with UMass our plans for this program.

- **miniUSH2A (*USH2A*-related IRDs):** This program, which we refer to as the miniUSH2A program, is targeting IRDs associated with mutations in the *USH2A* gene, including Usher 2A and *USH2A*-associated non-syndromic autosomal recessive retinitis pigmentosa. UMMS generated and evaluated several *USH2A* minigene constructs in *in vitro* experiments and we are planning to evaluate their efficacy in animals. The animal experiments were delayed as a result of transitioning the work from UMMS to us. We are discussing with UMass our plans for this program.

IC-500: HtrA1 Inhibitor

IC-500 is our preclinical product candidate for the treatment of GA secondary to AMD and potentially other age-related retinal diseases.

We are currently evaluating this program in light of available scientific and clinical information about this mechanism of action and our strategic goals. We do not currently expect to submit an investigational new drug application, or IND, to the FDA for IC-500 during the first half of 2024, as previously planned.

Business Development and Financing Activities

As we prepare for the potential marketing approval and potential commercial launch of ACP, progress our research and development programs and evaluate our overall strategic priorities, we continue to pursue selective business development and financing opportunities that advance us toward our strategic goals. We plan to continue to evaluate, on a selective and targeted basis, opportunities to obtain rights to additional product candidates and technologies for retinal diseases, with a focus on additional sustained release delivery technologies for ACP.

Please see our Annual Report on Form 10-K for the year ended December 31, 2022 for information about our exclusive license agreement with DelSiTech for its sustained release delivery technology for ACP and our asset purchase agreement with Opus Genetics Inc., or Opus, for our former preclinical stage gene therapy product candidates, IC-100 and IC-200.

For information about our $250.0 million term loan facility, or the 2022 Term Loan Facility, with Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or SVB, and our follow-on public offering completed in December 2022, please see the Liquidity and Capital Resources section of this Management' s Discussion and Analysis of Financial Condition and Results of Operations. We believe we have sufficient financial resources to launch ACP for GA in the United States, if approved based on our current expectations.

Financial Matters

As of March 31, 2023, we had approximately $599.9 million in cash, cash equivalents and available-for-sale securities. We estimate that our cash, cash equivalents, available for sale securities and committed loan facilities will be sufficient to fund our planned capital expenditure requirements, debt service obligations and operating expenses through at least the next twelve

months. These estimates do not include any potential new borrowings under the 2022 Term Loan Facility with Hercules and SVB beyond the $25.0 million that we plan to borrow during 2023 based on our achievement of the performance milestone related to the FDA's acceptance of our NDA for marketing approval of avacincaptad pegol for the treatment of GA secondary to AMD. In the event that SVB or any successor is unable to fund its portion of the commitments for the $25 million tranche that the we plan to borrow as a result of recent events, including the FDIC takeover of SVB and the subsequent sale of SVB's successor, Silicon Valley Bridge Bank, to First-Citizens Bank & Trust Company in March 2023, we do not believe such failure to fund would have a material effect on our cash balances or financial condition.

Financial Operations Overview

Revenue

As we have no products approved for sale, we do not expect to receive any revenue related to our product candidates until we obtain regulatory approval for and commercialize such products, or until we potentially enter into agreements with third parties for the development and commercialization of our product candidates. For example, if the FDA approves our NDA for marketing approval of avacincaptad pegol for the treatment of GA secondary to AMD and we successfully launch ACP in the United States, we expect to generate revenues from product sales.

Our ability to become and remain profitable depends on our ability to generate revenues in excess of our expenses. Our ability to generate revenues from product sales is dependent on our obtaining marketing approval for and commercializing our product candidates or any product candidates we may in-license or acquire. We may be unsuccessful in our efforts to develop and commercialize product candidates or in our efforts to in-license or acquire additional product candidates. Even if we succeed in developing and commercializing one or more of our product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

Research and Development Expenses

Our research and development expenses primarily consist of costs associated with the manufacturing, development, and preclinical and clinical testing of our product candidates and costs associated with our gene therapy research programs. Our research and development expenses consist of:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, contract development and manufacturing organizations, or CDMOs, and other vendors for the production and analysis of drug substance, drug product and finished goods; and
- employee-related expenses for employees dedicated to research and development activities, including salaries, benefits and share-based compensation expense.

Research and development expenses also include costs of acquired product licenses, in-process research and development, and related technology rights where there is no alternative future use, costs of prototypes used in research and development, consultant fees and amounts paid to collaborative partners.

All research and development expenses are charged to operations as incurred in accordance with Financial Accounting Standards Board, Accounting Standards Codification, or ASC, 730, *Research and Development.* We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we record expenses by functional department. Accordingly, we do not allocate expenses to individual projects or product candidates, although we do allocate some portion of our research and development expenses by project area or product candidate, as shown below.

The following table summarizes our research and development expenses for the three months ended March 31, 2023 and March 31, 2022:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Avacincaptad Pegol	$ 27,328	$ 14,169
IC-500: HtrA1	316	695
Other gene therapy	51	40
Prior product candidate IC-100	—	(320)
Prior product candidate IC-200	—	(298)
Personnel-related	8,726	5,512
Share-based compensation	5,541	2,661
Other	121	98
Total	$ 42,083	$ 22,557

As we continue our ongoing clinical trials and the OLE study and continue our ongoing and planned manufacturing and lifecycle management activities for avacincaptad pegol, we expect our research and development expenses for avacincaptad pegol to increase. We expect our research and development expenses for our minigene research programs to increase as we plan for and initiate additional preclinical development and manufacturing activities. We expect our research and development expenses for IC-500 to decrease. Our research and development expenses may increase if we in-license or acquire any new product candidates or technologies or if we commence any new development programs.

See the "Liquidity and Capital Resources" section of this Quarterly Report on Form 10-Q for more information regarding our current and future financial resources and our expectations regarding our research and development expenses and funding requirements.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation expense, in our executive, legal, finance, business development, commercial operations, human resources, investor relations and information technology functions. Other general and administrative expenses include facility costs and professional fees for legal, including patent-related, services and expenses, consulting and accounting services, and travel expenses.

We expect our general and administrative expenses to increase as we continue to hire personnel for our commercial organization, including sales, marketing, access and reimbursement and operations personnel, and as we continue to build our capabilities for the commercial launch of ACP, if approved. Our general and administrative expenses may further increase if the market opportunity for avacincaptad pegol exceeds our current expectations and we need to hire additional commercialization personnel and/or incur additional outside service fees in order to commercialize ACP, if approved. Our general and administrative expenses may also increase if we choose to hire additional personnel and incur additional fees and expenses for our general and administrative function areas. In light of the pending acquisition of our company by Astellas, we anticipate incurring additional legal, accounting and other advisory fees in relation to the transactions contemplated by the Merger Agreement and the consummation thereof.

Interest Income, Net

Interest income, net, consists of interest income earned on our cash, cash equivalents and marketable securities offset by interest expense recognized on our debt.

We currently have invested our cash, cash equivalents and available for sale securities in money market funds, U.S. Treasury securities, investment-grade corporate debt securities, asset-backed securities, and debt instruments issued by foreign governments. Interest income earned is offset by amortization of premiums and accretion of discounts to maturity on our marketable securities.

Interest expense consists of the accretion of debt discount, contractual interest costs and the amortization of debt issuance costs related to our debt. Debt discount is accreted, and debt issuance costs are amortized, to interest expense using the effective interest rate method over the term of the debt. Our consolidated balance sheets reflect debt, net of the debt discount, debt issuance costs paid to the lender and other third-party costs.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses and share-based compensation described in greater detail below. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. Of those policies, we believe that the following accounting policies are the most critical to aid our stockholders in fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to expenses related to our CROs, CDMOs and other vendors in connection with research and development and manufacturing activities.

We base our expenses related to CROs and CDMOs on our estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of Three Month Periods Ended March 31, 2023 and 2022

	Three months ended March 31,		Increase (Decrease)
	2023	2022	
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 42,083	$ 22,557	$ 19,526
General and administrative	31,758	12,113	19,645
Total operating expenses	73,841	34,670	39,171
Loss from operations	(73,841)	(34,670)	39,171
Interest income, net	3,461	133	3,328
Other (expense) income, net	(1,849)	1	(1,850)
Loss before income tax benefit	(72,229)	(34,536)	37,693
Income tax benefit	—	—	—
Net loss	$ (72,229)	$ (34,536)	$ 37,693

Research and Development Expenses

Our research and development expenses were $42.1 million for the three months ended March 31, 2023, an increase of $19.5 million compared to $22.6 million for the three months ended March 31, 2022. The increase in research and development expenses for the three months ended March 31, 2023 was primarily due to a $13.2 million increase in costs associated with avacincaptad pegol, including the ongoing GATHER2 trial, increased manufacturing activities and the initiation of the OLE study. In addition, the increase in research and development expenses was due to a $6.1 million increase in personnel costs, including share-based compensation associated with additional research and development staffing. The increase in research and development expenses was partially offset by a $0.4 million decrease in costs associated with IC-500. The decreased costs for IC-500 primarily reflect decreased manufacturing and preclinical development activities.

General and Administrative Expenses

Our general and administrative expenses were $31.8 million for the three months ended March 31, 2023, an increase of $19.6 million compared to $12.1 million for the three months ended March 31, 2022. The increase in general and administrative expenses for the three months ended March 31, 2023 was primarily due to increases in personnel costs, including share-based compensation associated with staffing for commercial preparation.

Interest Income, net

Interest income, net for the three months ended March 31, 2023 was $3.5 million compared to interest income of $133 thousand for the three months ended March 31, 2022. Interest income for the three months ended March 31, 2023 was partially offset by $3.0 million of interest expense which was due to our borrowings under the 2022 Term Loan Facility. There was no interest expense for the three months ended March 31, 2022. The increase in interest income for the three months ended March 31, 2023 was primarily due to rising interest rates and an increase in our cash equivalents and marketable securities average balances.

Other (Expense) Income, net

Other expense for the three months ended March 31, 2023 was $1.8 million compared to other income of $1 thousand for the three months ended March 31, 2022. During the quarter ended March 31, 2023, we recognized a $1.9 million expense associated with the impairment of our investment in Opus Genetics Inc. This expense was partially offset by income primarily related to exchange rate fluctuations associated with foreign currency transactions.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily through private placements of our common stock and preferred stock, venture debt borrowings, funds received under our prior Fovista royalty purchase and sale agreement with

Novo Holdings A/S, our initial public offering, which we closed in September 2013, funds we received under a prior agreement with Novartis Pharma AG related to the licensing and commercialization of Fovista, funds we received in connection with our acquisition of Inception 4, Inc., or Inception 4, in October 2018, our follow-on public offerings, which we closed in February 2014, December 2019, June 2020, July 2021, October 2021 and December 2022 and borrowings under the 2022 Term Loan Facility with Hercules and SVB.

In July 2022 we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules and SVB for the 2022 Term Loan Facility, which consists of several tranches of potential financing in an aggregate principal amount of up to $250.0 million. The first tranche consisted of a term loan advance in the amount of $50.0 million funded upon execution of the Loan Agreement on July 26, 2022. An aggregate of $150.0 million may be drawn at our option, in three separate tranches, subject to our achievement of specified performance milestones relating to development and regulatory events for avacincaptad pegol, as described below in "—Contractual Obligations and Commitments". We met the first milestone under the Loan Agreement and in December 2022 drew the second tranche consisting of a term loan advance in the amount of $50.0 million. We believe we have met the second milestone under the Loan Agreement and can draw the third tranche consisting of a term loan in the amount of $25.0 million, which we plan to draw in 2023. An additional $50.0 million is available subject to the approval of the lenders' investment committee in its discretion. Loans outstanding under facility bear interest at a floating interest rate per annum equal to the greater of either (i) (x) the lesser of the Wall Street Journal prime rate and 6.25% plus (y) 4.00% or (ii) 8.75%, capped at 10.25%. The facility matures in August 2027 and has an initial interest-only payment period of 42 months, which may be extended to up to 60 months upon the satisfaction of certain conditions.

We currently have an effective universal shelf registration statement on Form S-3, or the March 2021 Shelf Registration, on file with the SEC registering for sale from time to time up to $300.0 million of common stock, preferred stock, debt securities, depositary shares, subscription rights, warrants and/or units in one or more registered offerings, of which $100.0 million may be offered, issued and sold under an "at-the-market" Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC. We also have an automatically effective shelf registration statement on Form S-3, or the October 2021 Shelf Registration, pursuant to which we may offer and sell an indeterminate amount of shares of common stock, preferred stock, debt securities, depositary shares, subscription rights, warrants and/or units in one or more registered offerings.

In July 2021, we closed an underwritten public offering in which we sold 13,397,500 shares of our common stock under the March 2021 Shelf Registration, which included the exercise in full of the underwriters' option to purchase an additional 1,747,500 shares of our common stock, at a price to the public of $8.60 per share and at a price to the underwriters of $8.084 per share. The net proceeds from the public offering, after deducting underwriting discounts and commissions and other offering expenses payable by us totaling approximately $7.4 million, were approximately $107.8 million.

In October 2021, we closed an underwritten public offering in which we sold 10,350,000 shares of our common stock, under the October 2021 Shelf Registration, which included the exercise in full of the underwriters' option to purchase an additional 1,350,000 shares of our common stock, at a price to the public of $16.750 per share and at a price to the underwriters of $15.745 per share. The net proceeds from the public offering, after deducting underwriting discounts and commissions and other offering expenses payable by us totaling approximately $10.8 million, were approximately $162.6 million.

In December 2022, we completed an underwritten public offering in which we sold 15,352,500 shares of our common stock under the October 2021 Shelf Registration, which included the exercise in full of the underwriters' option to purchase 2,002,500 shares of our common stock, at a price to the public of $22.50 per share and at a price to the underwriters of $21.150 per share. The net proceeds from the December 2022 public offering, after deducting underwriting discounts and commissions and other expenses payable by us totaling approximately $21.1 million, were approximately $324.3 million.

We have not yet issued and sold any shares of our common stock under the ATM Agreement.

Cash Flows

As of March 31, 2023, we had cash, cash equivalents and available-for-sale securities totaling $599.9 million. We currently have invested our cash, cash equivalents and available for sale securities in money market funds, U.S. Treasury securities, certain asset-backed securities and certain investment-grade corporate debt securities.

The following table shows a summary of our cash flows for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating Activities	$ (50,593)	$ (37,512)
Investing Activities	39,272	(34,148)
Financing Activities	2,589	2,080
Net change in cash and cash equivalents	$ (8,732)	$ (69,580)

Cash Flows from Operating Activities

Net cash used in operating activities was $50.6 million and $37.5 million for the three months ended March 31, 2023 and 2022, respectively, which primarily related to net cash used to fund our avacincaptad pegol clinical trials and manufacturing activities and commercial planning for potential launch of avacincaptad pegol, if approved, our preclinical development of IC-500, our gene therapy research programs and to support our general and administrative operations.

See "—Funding Requirements" below for a description of how we expect to use our cash for operating activities in future periods.

Cash Flows from Investing Activities

Net cash provided by investing activities was $39.3 million for the three months ended March 31, 2023, which primarily related to the maturity of marketable securities. Net cash used in investing activities was $34.1 million for the three months ended March 31, 2022, which primarily related to the purchases of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $2.6 million and $2.1 million for the three months ended March 31, 2023 and 2022, respectively, which primarily consisted of proceeds related to stock option exercises and purchases made under our employee stock purchase plan.

Funding Requirements

ACP is in clinical development, IC-500 is in preclinical development, and we are exploring multiple sustained release delivery technologies for ACP and advancing multiple gene therapy research programs. We expect our research and development expenses to increase as we pursue these programs as currently planned. We could incur additional research and development expenses if we modify or further expand the scope of our clinical trials, such as our initiation of the OLE study for ACP in GA secondary to AMD, our preclinical development programs or our gene therapy research programs, or if we in-license or acquire, and undertake development of, additional product candidates and technologies, including additional sustained release delivery technologies for ACP and any promising product candidates that emerge from our gene therapy research programs. We could also incur additional research and development expenses if, for example, we are required by the FDA, the EMA or regulatory authorities in other jurisdictions, or if we otherwise decide, to perform clinical trials and/or nonclinical or other studies in addition to those we currently expect to conduct. If we experience delays or disruptions to our research and development programs, including delays in patient enrollment or issues with patient retention or patients missing scheduled visits and treatments, if we experience issues with our preclinical development programs, such as unfavorable toxicology or other preclinical data, if we experience issues with the manufacture and supply of product candidates, including issues with process development or manufacturing scale-up activities, whether such delays or disruptions are due to the COVID-19 pandemic or other reasons, we could incur additional and unexpected expenses as a result of such delays or disruptions and our business and financial results may be materially impacted. Furthermore, if we successfully develop and expect to obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We have started incurring these expenses as we prepare for the potential commercialization of ACP. We are party to agreements with Archemix with respect to ACP, DelSiTech with respect to formulations of ACP with DelSiTech's silica-based sustained release delivery technology, the former equityholders of Inception 4 with respect to IC-500, and UMass with respect to any potential product candidates from our miniCEP290 program, in each case, that impose significant milestone payment obligations on us if we or a potential collaborator achieves specified clinical, regulatory and commercial milestones with respect to these product candidates, as well as certain royalties on net sales with respect to formulations of ACP with DelSiTech's silica-based sustained release delivery technology and any product candidates we choose to develop from our miniCEP290 program. It is likely that any future in-

licensing or acquisition agreements that we enter into with respect to additional product candidates or technologies would include similar obligations.

We expect that we will continue to incur significant expenses as we:

- build our commercial operations and sales, marketing and distribution capabilities for ACP;
- expand our outsourced manufacturing capabilities for ACP;
- continue the development of ACP in GA, STGD1 and potentially other indications;
- seek marketing approval for ACP and any other product candidates that successfully complete clinical trials;
- in-license or acquire the rights to, and pursue the development of, other product candidates or technologies for retinal diseases, such as sustained release delivery technologies for ACP;
- continue the development of IC-500 and pursue our gene therapy research programs;
- maintain, expand and protect our intellectual property portfolio;
- hire additional commercial, medical affairs, clinical, regulatory, pharmacovigilance, manufacturing, quality control, quality assurance and scientific personnel; and
- expand our general and administrative functions to support our future growth.

As of March 31, 2023, we had approximately $599.9 million in cash, cash equivalents and available-for-sale securities. We estimate that our cash, cash equivalents, available for sale securities and committed loan facilities will be sufficient to fund our planned capital expenditure requirements, debt service obligations and operating expenses through at least the next twelve months. These estimates do not include any potential new borrowings under the 2022 Term Loan Facility with Hercules and SVB beyond the $25.0 million that we plan to borrow during 2023 based on our achievement of the performance milestone related to the FDA's acceptance of our NDA for marketing approval of avacincaptad pegol for the treatment of GA secondary to AMD. In the event that SVB or any successor is unable to fund its portion of the commitments for the $25 million tranche that the we plan to borrow as a result of recent events, including the FDIC takeover of SVB and the subsequent sale of SVB’s successor, Silicon Valley Bridge Bank, to First-Citizens Bank & Trust Company in March 2023, we do not believe such failure to fund would have a material effect on our cash balances or financial condition.

Although we believe we have sufficient financial resources to launch ACP for GA secondary to AMD in the United States, if approved with labeling consistent with our expectations, we may need additional funding to continue to commercialize ACP for GA, if approved. We expect we will require substantial, additional funding in order to complete the activities necessary to develop and commercialize ACP for other indications, a sustained release delivery technology for ACP or any of our other product candidates. At this time, we cannot reasonably estimate the total remaining costs necessary to complete development, to complete process development and manufacturing scale-up and validation activities and to potentially seek marketing approval for ACP for any other indication, a sustained release delivery technology for ACP or for any of our other product candidates.

Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory filings and reviews of our product candidates, including regulatory review of our filed NDA and the planned submission of MAAs for ACP in GA secondary to AMD;
- the timing, scope and costs of establishing a commercial infrastructure for potential commercialization of ACP, including the hiring and deployment of a sales force and the establishment of sales, marketing and distribution capabilities;
- the scope, progress, costs and results of process development, manufacturing scale-up and validation activities, analytical method development and qualification, and stability studies associated with ACP and our other product candidates;
- the scope, progress, costs and results of our current and future ACP clinical programs and any further development we may undertake;
- the extent to which we in-license or acquire rights to, and undertake research or development of, additional product candidates or technologies, including sustained release delivery technologies for ACP;

- the extent of our debt service obligations and our ability, if desired, to refinance any of our existing debt on terms that are more favorable to us;
- the scope, progress, costs and results of our efforts to develop IC-500, including activities to establish manufacturing capabilities and complete other preclinical development activities;
- the scope, progress, costs and results from our gene therapy research programs, including costs related to the in-license and future development of any promising product candidates and technologies that emerge from these programs;
- the timing and extent of delays or disruptions to our research and development programs as a result of the COVID-19 pandemic and other macro-economic events;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending intellectual property-related claims; and
- subject to receipt of marketing approval, net revenue received from commercial sales of any of our product candidates, after milestone payments and royalty payments that we would be obligated to make.

Our ability to raise adequate additional financing when needed, and on terms acceptable to us, will depend on many factors. These factors include investors' perceptions of the potential success of our ongoing business, including the development of our product candidates and other programs, and the potential future growth of our business. Additionally, these factors include general market conditions that also affect other companies. For example, the COVID-19 pandemic and other macro-economic events, such as the current high levels of inflation, and governmental responses to those events have caused volatility and uncertainty in the financial markets as well as additional volatility in the price of our stock, which may result in prospective investors being less likely to invest new capital. These factors may make raising capital difficult, and may result in us accepting terms that are unfavorable to us, especially if we are in need of financing at the particular time. Although we were successful in raising approximately $324.3 million in net proceeds in an underwritten public offering of our common stock in December 2022, we may not be able to successfully raise additional capital in the future. The size of our company and our status as a company listed on The Nasdaq Global Select Market, or Nasdaq, may also limit our ability to raise financing. For example, Nasdaq listing rules generally limit the number of shares we may issue in a private placement to a number less than 20% of the number of shares of our common stock outstanding immediately prior to the transaction, unless we issue such shares at a premium, which investors may be unwilling to accept, or unless we obtain shareholder approval, which can be expensive and time-consuming and can add risk to our ability to complete the financing transaction. If we are unable to raise additional funds when needed, we may be required to delay or reduce our future commercialization efforts, or delay, reduce or terminate the development of one or more of our product candidates.

We may require additional funding beyond what we currently expect due to unforeseen or other reasons. Our costs may exceed our expectations if the timeline for potential commercial launch of ACP is accelerated, if we need to establish commercial infrastructure or capabilities, including hiring additional personnel or conducting additional disease-state awareness activities, to a greater extent than we have planned. Our costs may also exceed our expectations if we experience an issue with manufacturing, such as issues with process development, scale-up and validation, or establishing and qualifying second source suppliers and ensuring adequate inventory for our expected needs, including potential launch of ACP; if we experience an issue in our clinical trials, such as issues with patient enrollment, the retention of enrolled patients, enrolled patients maintaining scheduled visits and receiving scheduled treatments, or the availability of drug supply; if we experience an issue in our preclinical development programs, such as unfavorable toxicology or other preclinical data; or if we modify or further expand the scope of our clinical trials, preclinical development programs or gene therapy research programs. Our costs may also exceed our expectations for other reasons, for example, if we are required by the FDA, the EMA, or regulatory authorities in other jurisdictions to perform clinical trials or nonclinical or other studies in addition to those we currently expect to conduct. For example, we believe that the data from the GATHER2 trial, together with other available data, are sufficient to support applications for marketing approval in the United States, the European Union and the United Kingdom. We may subsequently decide to, or be required by regulatory authorities to, conduct additional clinical trials or nonclinical studies of ACP in order to seek or maintain marketing approval or qualify for reimbursement approval. In addition, the COVID-19 pandemic and other macroeconomic events may result in disruptions to the progress of the GATHER2 or STAR trials or the OLE study, including slowing patient enrollment in STAR or causing enrolled patients in either trial to miss their scheduled visits or drop out in greater numbers than we expect, or disruptions to our other research and development programs, which could cause us to continue to expend our cash resources while not progressing our research and development programs as expeditiously as we would have had the pandemic not occurred or persisted. As a result of any of the above, we may need or may seek to obtain additional funding for our continuing operations sooner or in greater amounts than expected.

Our need for additional financing may continue even if we are able to successfully obtain regulatory approval and launch ACP in GA secondary to AMD. Our future commercial revenues, if any, will be derived from product sales, which may not be available or become substantial for a period of time following launch. In addition, if approved, our products may not achieve commercial success. Even if those products are successful and we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Under most, if not all, of the foregoing circumstances, we may need to obtain substantial additional financing to achieve our business objectives.

Contractual Obligations and Commitments

As disclosed in "Note 8 — Commitments and Contingencies" in the notes to the financial statements filed with this Quarterly Report on Form 10-Q, we have exposure for certain commitments and contingencies.

We also have letter agreements with certain employees that require the funding of a specific level of payments if certain events, such as a termination of employment by the employee for good reason or by us without cause, in each case in connection with a change of control, occur. For a description of these obligations, see our definitive proxy statement on Schedule 14A for our 2023 annual meeting of stockholders, as filed with the SEC on April 5, 2023.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development, manufacturing and commercial planning activities. Expenditures to CROs, CDMOs and other service providers represent significant costs in preclinical and clinical development and commercial planning. Subject to required notice periods and our obligations under binding purchase orders and any cancellation fees that we may be obligated to pay, we can elect to discontinue the work under these agreements at any time. In addition to the commercial manufacturing and supply agreement we entered into with Agilent for ACP drug substance (see Note 7 - Commitments and Contingencies), we may also enter into additional collaborative research and development, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Merger Agreement

On April 28, 2023, we and Astellas entered into the Merger Agreement pursuant to which, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into our company, with our company surviving the Merger as a wholly owned subsidiary of Astellas. Consummation of the Merger is subject to customary closing conditions, including, without limitation, obtaining the required regulatory approvals and approval by our stockholders. The Merger Agreement contains certain termination rights for us and Astellas. If the Merger Agreement is terminated under specified circumstances, we will be required to pay Astellas a termination fee of approximately $222.4 million.

2022 Term Loan Facility

On July 26, 2022, or the Closing Date, we and certain of our subsidiaries, or the Subsidiary Borrowers, entered into the Loan Agreement with Hercules in its capacity as administrative agent and collateral agent, or the Agent, and as a lender, SVB and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders, which we refer to collectively as the Lenders. The Loan Agreement provides for term loans in an aggregate principal amount of up to $250.0 million under multiple tranches, or the 2022 Term Loan Facility, available as follows: (i) a term loan advance in the amount of $50.0 million, which was drawn on the Closing Date; (ii) subject to our announcement that the GATHER2 trial evaluating avacincaptad pegol in GA has achieved its protocol-specified primary endpoint and that we have a sufficient clinical data package to support the submission of an NDA to the FDA for avacincaptad pegol in GA, or Milestone 1, a second tranche consisting of term loan advances in the aggregate principal amount of $50.0 million available at our option beginning on the date that Milestone 1 is achieved through December 15, 2022, which we drew in December 2022; (iii) subject to our submission of an NDA to the FDA for avacincaptad pegol in GA and the FDA accepting such NDA for review, or Milestone 2, a third tranche consisting of term loan advances in the aggregate principal amount of $25.0 million, available at our option beginning on the date that Milestone 2 is achieved through September 30, 2023; (iv) subject to FDA approval of avacincaptad pegol in GA with a label generally consistent with that sought in our NDA, or Milestone 3, a fourth tranche consisting of term loan advances in the aggregate principal amount of $75.0 million, available at our option beginning on the date that Milestone 3 is achieved and continuing through the earlier of (x) September 30, 2024 and (y) the date that is 90 days after the date that Milestone 3 is achieved; and (v) subject to approval by the Lenders' investment committee in its discretion, a fifth tranche of additional term loans in an aggregate principal amount of up to $50.0 million, available on or before the Amortization Date (as defined below). We believe we have achieved Milestone 2 and plan to borrow the full $25.0 million tranche that is available during 2023. With the exception of the first and second $50.0 million tranches available on the Closing Date and in December 2022, each of the tranches may be drawn down in $5.0 million increments at our election, upon achievement of the relevant milestones specified in the Loan Agreement. We have agreed to use the proceeds of the 2022 Term Loan Facility for working capital and general corporate purposes.

Notwithstanding limitations and restrictions imposed by covenants in the Loan Agreement, we are permitted to engage in certain specified transactions. For example, the terms of the Loan Agreement provide that we may issue convertible notes in an aggregate principal amount of not more than $400.0 million, provided that such notes are unsecured, have a maturity date no earlier than six months following the Maturity Date, and meet certain other conditions. The Loan Agreement also provides that we may enter into royalty interest financing transactions that are subordinated to the 2022 Term Loan Facility, have a maturity date no earlier than six months following the Maturity Date, and meet certain other conditions. Following the achievement of Milestone 3, the Loan Agreement also provides for a possible additional revolving credit facility of up to $50.0 million, which will be formula-based and backed by our accounts receivables. This potential revolving credit facility is not an existing facility under the Loan Agreement, is not committed, and is subject to agreement among us and the Lenders. We also may enter into non-exclusive and exclusive licensing arrangements or otherwise transfer non-core intellectual property without the consent of the Lenders, and can enter into non-exclusive and certain specified exclusive licensing arrangements with respect to core intellectual property. We may also enter into certain permitted acquisitions, subject to a limit on total cash consideration for acquisitions consummated during specified periods. Additionally, we must provide the Lenders the opportunity to invest up to $10.0 million in any equity financing, subject to certain exclusions, that is broadly marketed to multiple investors and in which we receive net cash proceeds of $75.0 million or more in any one or series of related financings (or in the case of such equity financing that is a registered offering, use its commercially reasonable efforts to provide such opportunity to the Lenders).

The 2022 Term Loan Facility will mature on August 1, 2027, or the Maturity Date. The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) (x) the lesser of the Wall Street Journal prime rate and 6.25% plus (y) 4.00% or (ii) 8.75%. The per annum interest rate is capped at 10.25%. Accrued interest is payable monthly following the funding of each term loan. We may make payments of interest only, without any loan amortization payments, for a period of forty-two (42) months following the Closing Date, which period may be extended to the Maturity Date if (i) Milestone 3 has been achieved and (ii) no default or event of default exists under the Loan Agreement. At the end of this interest only period, or the Amortization Date, we are required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly installments.

As collateral for the obligations under the 2022 Term Loan Facility, we have granted to the Agent for the benefit of the Lenders a senior security interest in substantially all of our and each Subsidiary Borrower's property, inclusive of intellectual property, with certain limited exceptions set forth in the Loan Agreement.

The Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent, or the Qualified Cash, during the period commencing on May 15, 2023 through August 14, 2024. Effective as of July 26, 2023, we and certain of the Subsidiary Borrowers will be required to (i) maintain all of their respective operating accounts, depository accounts and excess cash in the United States with SVB or an SVB affiliate and (ii) obtain any business card, letter of credit and other material cash management services in the United States exclusively from SVB or an SVB affiliate. Commencing on August 15, 2024, we will also be required to maintain a certain minimum amount of trailing six-month net product revenue from the sale of avacincaptad pegol, tested on a quarterly basis. The revenue covenant will be waived at any time at which we (x) (i) maintain a market capitalization in excess of $600.0 million and (ii) maintain Qualified Cash in an amount greater than or equal to 50% of the outstanding 2022 Term Loan Facility at such time or (y) maintain Qualified Cash in an amount greater than or equal to 90% of the outstanding 2022 Term Loan Facility at such time. Upon the occurrence of an event of default, including a material adverse change, subject to certain exceptions, on our business, operations, properties, assets or financial condition, and of the Subsidiary Borrowers taken as a whole, and subject to any specified cure periods, all amounts owed by us may be declared immediately due and payable by the Lenders. As of March 31, 2023, we were in compliance with all applicable covenants under the Loan Agreement.

In addition, we are required to make a final payment fee, or the End of Term Charge, upon the earlier of (i) the Maturity Date or (ii) the date we prepay, in full or in part, the outstanding principal balance of the 2022 Term Loan Facility. The End of Term Charge is 4.25% of the aggregate original principal amount of the term loans repaid or repaid under the Loan Agreement.

We may, at our option, prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.0% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the Closing Date, (ii) 1.5% of the principal amount prepaid if the prepayment occurs on or after the first anniversary and prior to the second anniversary of the Closing Date, and (iii) 0.75% of the principal amount prepaid if the prepayment occurs on or after the second anniversary and prior to the third anniversary of the Closing Date. Upon closing of the Merger Agreement, we expect to prepay in full all outstanding obligations under the Loan Agreement.

The 2022 Term Loan Facility is expected to be paid off in connection with the closing of the Merger. We are restricted between signing and closing of the Merger in our ability to make additional drawdowns under the 2022 Term Loan Facility, but may draw an amount of $25.0 million in connection with Milestone 2, which milestone we believe was achieved in February 2023, and an amount of $75.0 million in connection with Milestone 3, if achieved by us, if the Merger has not been consummated by specific dates set forth in the Merger Agreement.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and available for sale securities of $599.9 million as of March 31, 2023, consisting of cash and investments in money market funds, U. S. Treasury securities, corporate debt securities and asset-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term securities. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We regularly maintain domestic cash deposits in FDIC insured banks that exceed the FDIC insurance limits. Bank failures, events involving limited liquidity, default, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a failure or liquidity crisis.

We contract with CDMOs, CROs and certain other vendors to perform services outside of the United States. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. As of March 31, 2023, substantially all of our total liabilities were denominated in the U.S. dollar.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

You should carefully consider the following risks and uncertainties, and those risks and uncertainties discussed in "Part I, Item 1A, Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 1, 2023 together with all of the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The risk factor disclosure in our Annual Report on Form 10-K for the year ended December 31, 2022 is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the risks described in our Annual Report on Form 10-K for the year ended December 31, 2022 actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Pending Merger with Astellas

We may not complete the pending Merger with Astellas within the timeframe anticipated, or at all, which could have a material adverse effect on our business, financial condition or operations.

On April 28, 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Astellas US Holding, Inc., a Delaware corporation, or Astellas, Berry Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Astellas, or Merger Sub, and solely as provided by Section 8.10(b) of the Merger Agreement, Astellas Pharma Inc., a company organized under the laws of Japan, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into our company, or the Merger, with our company surviving the Merger as a wholly owned subsidiary of Astellas. At the effective time of the Merger, each share of our common stock issued and outstanding as of immediately prior to the effective time (other than Excluded Shares (as defined in the Merger Agreement) and Dissenting Shares (as defined in the Merger Agreement)) will be cancelled and automatically converted into the right to receive cash in an amount equal to $40.00, without interest and subject to any withholding of taxes.

Consummation of the Merger is subject to customary closing conditions, including, without limitation, approval by our stockholders, the absence of certain legal impediments, no material adverse effect having occurred since the signing of the Merger Agreement, the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other antitrust authority specified in the Merger Agreement, solely to the extent the approval of any such authority is required in connection with the Merger. We currently expect the Merger and the other transactions contemplated by the Merger Agreement to close in the third calendar quarter of 2023.

We cannot provide any assurance that the conditions to the consummation of the Merger will be satisfied or waived or that, if the Merger is consummated, it will be on the terms specified in the Merger Agreement or within the anticipated timeframe. If the Merger is not completed within the timeframe anticipated, or at all, we may be subject to a number of material risks or suffer a number of consequences in addition to the risks of continuing to operate our business. The price of our common stock may decline to the extent that current market prices of our common stock reflect assumptions that the Merger will be completed on a timely basis. We could be required to pay Astellas a termination fee of approximately $222.4 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement. The failure to complete the Merger also may result in negative publicity and negatively affect our relationship with our stockholders, employees, strategic partners, suppliers and lenders. Customers, prospective customers and investors in general may view the failure to consummate the Merger as a poor reflection on our business and prospects. If the Merger is not completed, the time and resources committed by our management team could have been devoted to pursuing other opportunities. We may also be required to devote significant time and resources to litigation related to the Merger or to any enforcement proceeding commenced against us to perform our obligations under the Merger Agreement. Furthermore, the granting of regulatory approvals by antitrust authorities could involve the imposition of additional conditions on the closing of the Merger. The imposition of such conditions or the failure or delay to obtain regulatory approvals could have the effect of delaying completion of the Merger or of imposing additional costs or limitations on us or may result in the failure to close the Merger.

The announcement and pendency of the Merger with Astellas could adversely affect our business, financial condition or operations.

Our efforts to complete the Merger with Astellas could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our business, financial condition or operations, or the price of our common stock. Uncertainty as to whether the Merger will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following consummation of the Merger. A substantial amount of our management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from our day-to-day operations. Uncertainty as to our future also could adversely affect our business and our relationship with collaborators, strategic partners, suppliers, prospective customers or regulators. For example, collaborators, suppliers, and other counterparties may defer decisions concerning us, or seek to change existing business relationships with us, whether pursuant to the terms of their existing agreements with us or otherwise. Changes to or termination of existing business relationships could adversely affect our financial condition and operations, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction, changes to the terms of the transaction or termination of the Merger Agreement.

In certain instances, the Merger Agreement requires us to pay a termination fee to Astellas, which could require us to use available cash that would have otherwise been available for general corporate purposes.

The Merger Agreement contains certain termination rights for us and Astellas. Subject to certain limitations, we or Astellas may terminate the Merger Agreement if the Merger is not consummated by midnight Eastern Time, on October 27, 2023, subject to an automatic 90-day extension in the event that all conditions other than the required antitrust approvals have been obtained or waived as of such date and a second automatic 90-day extension thereafter in the event that all conditions other than the required antitrust approvals have been obtained or waived as of such extended date, which we refer to as the End Date.

Upon termination of the Merger Agreement, under specified circumstances, we will be required to pay Astellas a termination fee of approximately $222.4 million. Such circumstances include where the Merger Agreement is terminated (i) in connection with the Company accepting a Superior Offer (as defined in the Merger Agreement) approved by our board of directors, (ii) due to our board of directors' change or withdrawal of, or failure to reaffirm, its recommendation of the Merger, or (iii) because our board of directors or our company intentionally breach their non-solicit obligations under the Merger Agreement in any material respects. This termination fee will also be payable if the Merger Agreement is terminated because our stockholders did not vote to adopt the Merger Agreement, the Merger is not consummated before the End Date, or we breach our representations, warranties or covenants in a manner that would cause the related closing conditions to not be met, and prior to any such termination, a proposal to acquire at least 50% of our stock or assets is communicated to our board of directors or publicly disclosed and within one year after termination of the Merger Agreement we enter into an agreement for, or consummate, such a transaction, whether or not the consummated transaction was the one contemplated by such proposal.

If the Merger Agreement is terminated under such circumstances, the termination fee we would be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses. Further, a failed transaction may result in negative publicity and a negative impression of us in the investment community. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business operations and financial condition, which in turn would materially and adversely affect the price of our common stock.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending Merger with Astellas.

We have incurred, and will continue to incur, significant costs and expenses, including legal, accounting and other advisory fees and other transaction costs, in connection with the pending Merger. We will be required to pay a substantial portion of these costs and expenses whether or not the Merger is completed. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities, generally requiring us to conduct our business in the ordinary course, consistent with past practice, in all material respects, and subjecting us to a variety of specified limitations absent Astellas' prior consent. These limitations include, among other things, restrictions on our ability to acquire other businesses and material assets (including certain governmental licenses and authorizations), dispose of material assets, make investments, enter into certain material contracts, repurchase or issue securities, pay dividends, make capital expenditures, take certain actions relating to intellectual property, terminate existing clinical trials or commence new clinical trials, amend our organizational documents and incur indebtedness. These restrictions could prevent us from pursuing strategic business opportunities, taking actions with respect to our business that we may consider advantageous and responding

effectively or on a timely basis to competitive pressures and industry developments, and may as a result materially and adversely affect our business, financial condition and operations.

The Merger Agreement contains provisions that could deter or make it difficult for a third party from proposing an alternative transaction or acquire our company prior to the consummation of the Merger.

The Merger Agreement contains provisions that make it difficult for us to entertain a third-party proposal for an acquisition of our company or an alternative transaction in lieu of the Merger. These provisions include our agreement not to solicit or initiate any additional discussions with third parties regarding other proposals for an acquisition of our company, as well as restrictions on our ability to respond to such proposals, subject to certain exceptions including fulfillment of certain fiduciary requirements of our board of directors. In addition, we could be required to pay Astellas a termination fee of approximately $222.4 million if the Merger Agreement is terminated under specific circumstances. These or other provisions in the Merger Agreement might discourage a third party with a potential interest in acquiring all or a significant part of the outstanding shares of our common stock from considering or proposing an acquisition, even one that may be deemed of greater value to our stockholders than the proposed Merger with Astellas. Furthermore, even if a third party elects to propose an acquisition of us, the potential competing acquirer may propose to pay a lower amount as a result of the termination fee that will become payable by us.

We may be targets of securities class action and derivative lawsuits which could result in substantial costs and may delay or prevent the Merger from being completed.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. The outcome of litigation is uncertain and we may not be successful in defending against future claims brought against us even if they are without merit. Regardless of the outcome of any lawsuits brought against us, such lawsuits could delay or prevent the Merger, divert the attention of our management and employees from our day-to-day business, result in substantial costs and otherwise adversely affect us financially. A potential adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the Merger, that injunction may delay or prevent the Merger from being completed, or from being completed within the anticipated timeframe, which may adversely affect our business, financial condition or operations.

Our executive officers and directors may have interests in the proposed Merger that are different from, or in addition to, those of our stockholders generally.

Our executive officers and directors may have interests in the proposed Merger that are different from the interests of our stockholders generally, including, among others, the acceleration of the vesting of equity awards and receipt of change in control or other severance payments in connection with the proposed Merger, continued indemnification and potentially continued service to the combined company.

These interests, among others, may influence, or appear to influence, our officers and directors and cause them to view the Merger differently from how our stockholders generally may view it.

Additional information regarding our executive officers and directors and their interests in the proposed Merger will be included in the proxy statement relating to the proposed Merger when it is filed with the SEC.

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

Recent Sales of Unregistered Securities

We did not sell any unregistered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 5. Other Information

None.

Item 6. Exhibits and Financial Statement Schedules

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

(2) Financial Statement Schedules

No financial statement schedules have been filed as part of this Quarterly Report on Form 10-Q because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

(3) Exhibits

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant, as amended April 16, 2019 (incorporated by reference to Exhibit 3.1 of the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2021)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-190643)
3.3	Amendment to Amended and Restated Bylaws of the Registrant, dated April 28, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 1, 2023)
10.1	Amendment No. 6 to 2019 Inducement Plan of the Registrant, dated February 23, 2023
10.2	Amendment No. 5 to Non-Employee Director Compensation Policy of the Registrant, dated February 23, 2023
10.3 +	Commercial Manufacturing and Supply Agreement, dated March 14, 2023, between the Registrant and Agilent Technologies, Inc.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document
104*	The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL

* Submitted electronically herewith.

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

Attached as Exhibit 101 to this Quarterly Report on Form 10-Q are the following formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2023 (unaudited) and December 31, 2022, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three month periods ended March 31, 2023 and 2022, (iii) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three month periods ended March 31, 2023 and 2022, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the three month periods ended March 31, 2023 and 2022 and (v) Notes to Condensed Financial Statements (unaudited).

SIGNATURES

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

IVERIC bio, Inc.

Date: May 10, 2023

By: /s/ David F. Carroll
David F. Carroll
Chief Financial Officer
(Principal Financial and Accounting Officer)

Amendment No. 6 to 2019 Inducement Stock Incentive Plan

AMENDMENT NO. 6 TO

2019 INDUCEMENT STOCK INCENTIVE PLAN

OF

IVERIC BIO, INC.

The 2019 Inducement Stock Incentive Plan (the "Plan") of IVERIC bio, Inc. (the "Company") is hereby amended as follows (all capitalized terms used and not defined herein shall have the respective meanings ascribed to such terms in the Plan):

1. Section 4(a)(1) of the Plan be and hereby is deleted in its entirety and the following is inserted in lieu thereof:

(1) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan for up to 7,600,000 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

3. Except as set forth herein, the Plan shall remain in full force and effect.

* * *

Approved by the Board of Directors on February 23, 2023.

AMENDMENT NO. 5 TO

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

OF

IVERIC BIO, INC.

The Non-Employee Director Compensation Policy (the "Policy") of IVERIC bio, Inc. (the "Company") is hereby amended as follows (all capitalized terms used and not defined herein shall have the respective meanings ascribed to such terms in the Policy):

1. The section in the Policy captioned "Equity Compensation" under the heading in the Policy captioned "Non-Employee Director Compensation" be and hereby is deleted in its entirety and the following is inserted in lieu thereof:

Equity Compensation

Initial Equity Grants. Upon his or her initial election or appointment to the Board, each New Non-Employee Director shall automatically, and without the need for any further action by the Board, be granted (a) an option (the "Initial Option Grant") under the Company's 2013 Stock Incentive Plan, as amended from time to time, or any successor or other new stock or equity incentive plan (the "Plan") to purchase such number of shares of the Company's common stock, par value $0.001 per share (the "Common Stock") as will yield a stock option award with a grant date fair value of $300,000 and (b) a grant (the "Initial RSU Grant") under the Plan of such number of restricted stock units for shares of Common Stock ("RSUs") as will yield a restricted stock unit award with a grant date fair value of $300,000, in the case of both of clauses (a) and (b), (i) based on the closing stock price or fair market value of the Common Stock on the date of grant, determined in a manner consistent with that described under the paragraph captioned "*General*" below and (ii) rounding to the nearest whole share. Unless otherwise provided at the time of grant, subject to each such person's continued service with the Company, (a) the Initial Option Grant will vest with respect to 1/36th of the shares subject to such option at the end of each successive one-month period following the grant date until the third anniversary of the grant date, (b) the Initial RSU Grant will vest with respect to 1/3rd of the shares underlying such grant at the end of each successive annual period following the grant date until the third anniversary of the grant date and (c) in the event of a "Change in Control Event" of the Company (as defined in the Plan), the Initial Option Grant shall immediately become fully vested and exercisable and the Initial RSU Grant shall immediately vest in full.

Annual Equity Grants. On the date of each annual meeting of stockholders of the Company, each non-employee director who has served on the Board since December 31 of the prior year, and is both serving as a director of the Company immediately prior to and immediately following such annual meeting, shall automatically, and without the need for any further action by the Board, be granted (a) an option (the "Annual Option Grant") under the Plan to purchase such number of shares of Common Stock as will yield a stock option award with a grant date fair value of $150,000 and (b) a grant (the "Annual RSU Grant") under the Plan of such number of RSUs as will yield a restricted stock unit award with a grant date fair value of $150,000, in the case of both of clauses (a) and (b), (i) based on the closing stock price or fair market value of the Common Stock on the

date of grant, determined in a manner consistent with that described under the paragraph captioned "*General*" below and (ii) rounding to the nearest whole share. Unless otherwise provided at the time of grant, subject to the non-employee director's continued service with the Company, (a) the Annual Option Grant will vest with respect to 1/12th of the shares subject to such option at the end of each successive one-month period following the grant date until the earlier of (1) the day that is one business day prior to the date of the next annual meeting and (2) the first anniversary of the grant date, at which time such option shall be fully vested and exercisable, (b) the Annual RSU Grant will vest with respect to all of the shares subject to such grant on the earlier of (1) the day that is one business day prior to the date of the next annual meeting and (2) the first anniversary of the grant date and (c) in the event of a "Change in Control Event" of the Company (as defined in the Plan), the Annual Option Grant shall immediately become fully vested and exercisable and the Annual RSU Grant shall immediately vest in full.

General. Each Initial Option Grant and each Annual Option Grant shall have a term of ten years from the date of the award. The exercise price of each option will be equal to the closing sale price (for the primary trading session) of the Common Stock on the national securities exchange on which the Common Stock is then traded on the date of grant (or if the date of grant is not a trading day on such exchange, the trading day immediately prior to the date of grant) or if the Common Stock is not then traded on a national securities exchange, the fair market value of the Common Stock on such date as determined by the Board.

The foregoing share amounts with respect to option and RSU grants to the non-employee directors shall be automatically adjusted in the event of any stock split, combination, recapitalization and other similar event affecting the Common Stock, all as provided for under the terms of the Plan.

The initial equity grants and the annual equity grants to the non-employee directors provided for herein shall be subject to the terms and conditions of the Plan and the terms of any option or RSU agreements entered into with each director in connection with such awards.

2. Except as set forth herein, the Plan shall remain in full force and effect.

* * *

Approved by the Board of Directors on February 23, 2023.

COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

This Commercial Manufacturing and Supply Agreement (this "Agreement") is entered into by and between AGILENT TECHNOLOGIES, INC., a Delaware corporation, having a principal office at 5301 Stevens Creek Blvd., Santa Clara, CA 95051 ("Agilent") and IVERIC BIO, INC., a Delaware corporation, having a principal office at 8 Sylvan Way, Parsippany, NJ 07054 ("Customer") effective as of March 14, 2023 (the "Effective Date"). Agilent and Customer are each referred to herein as a "Party" and together as the "Parties".

In consideration of the mutual covenants and promises set forth herein, the Parties hereby agree as follows:

1. SCOPE OF AGREEMENT

This Agreement, together with the Quality Agreement (as defined below) specifies the terms and conditions under which Agilent will manufacture and supply the Product (as defined below) to Customer and perform Manufacturing Services (as defined below) for Customer for commercial purposes.

2. DEFINITIONS

The following capitalized terms will have the meanings given for the purposes of this Agreement:

2.1 "[**] Process" means the manufacturing process for the Product with a nominal scale of [**], it being understood that the exact size of such scale may change as such process is developed.

2.2 "[**] Process" means the manufacturing process for the Product anticipated to have a nominal scale of [**], it being understood that the exact size of such scale may change as such process is developed.

2.3 "Affiliate" means any business entity which directly or indirectly controls, is controlled by, or is under common control with any Party to this Agreement. A business entity shall be deemed to "control" another business entity if (i) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or (ii) it has the de facto ability to control or direct the management of such business entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of fifty percent (50%) or more, "control" shall be deemed to exist at the maximum level of ownership allowed by such jurisdiction; provided, however, that there is de facto ability to direct or control its management.

2.4 "Anti-[**] Aptamer" means (i) an Aptamer that binds to [**] and (ii) all intermediates thereof.

2.5 "Active Pharmaceutical Ingredient (API)" has the meaning set forth in the Quality Agreement.

2.6 "Agilent Supply Interruption" has the meaning set forth in Section 4.10.

2.7 "Agilent IP" has the meaning set forth in Section 9.2.2.

2.8 "[**]" has the meaning set forth in Section [**].

2.9 "Aptamer" means (i) any pegylated or unpegylated naturally or non-naturally occurring oligonucleotide that binds to a Target and (ii) any pegylated or unpegylated oligonucleotide Derived from an oligonucleotide of clause (i) that binds to a Target.

2.10 "Batch" means a specific quantity of Product with a specified yield mutually agreed upon between Customer and Agilent as set forth in a Purchase Order that (a) is intended to have uniform character and quality within specified limits, and (b) is Processed according to a single manufacturing order during the same cycle of manufacture.

2.11 "Batch Documentation" has the meaning set forth in the Quality Agreement.

2.12 "Batch Production Record" has the meaning set forth in the Quality Agreement.

2.13 "Binding Forecast" has the meaning set forth in Section 4.1.1.

2.14 "Certificate of Analysis" has the meaning set forth in the Quality Agreement.

2.15 "Certificate of Compliance" has the meaning set forth in the Quality Agreement.

2.16 "cGMP" has the meaning set forth in the Quality Agreement.

2.17 "Change Management" means the procedure set forth in the Quality Agreement.

2.18 "Confidentiality Agreement" has the meaning set forth in Section 14.1.

2.19 "Cost" has the meaning set forth in Section 3.3.6.

2.20 "Customer IP" has the meaning set forth in Section 9.3.1.1.

2.21 "[**]" has the meaning set forth in Section [**].

2.22 "[**]" has the meaning set forth in Section [**].

2.23 "Deficiency Amount" has the meaning set forth in Section 4.11.1.

2.24 "Derived" means identified, obtained, developed, created, synthesized, designed or resulting from, based upon, containing or incorporating or generated from or conjugated to or complexed with (whether directly or indirectly or in whole or in part).

2.25 "Executed Batch Record" has the meaning set forth in the Quality Agreement.

2.26 "Facility" means either of Agilent's manufacturing facilities located at 5555 Airport Boulevard, Boulder, Colorado 80301 and at 7051 Eagle Blvd, Longmont, CO 80504, or such other manufacturing site agreed to by the Parties in writing.

2.27 "FDA" means the United States Food and Drug Administration or any successor organization.

2.28 "Finished Product" means any finished product incorporating the Product (including, for the avoidance of doubt, in any formulation or presentation, and whether in a pegylated or unpegylated form).

2.29 "Good Condition" means that at the time of delivery to Customer's carrier the Product supplied shall: (i) be the right Product; (ii) be in the right quantity in accordance with the manifest; (iii) be in the packaging agreed to by the Parties; (iv) be labeled in accordance with the Product registration; and (v) have no visible defect in the packaging or seal.

2.30 "Independent Laboratory" means a laboratory independent of each Party, mutually agreed in writing between the Parties and competent to determine the matters referred to in Section 8.2.3.5.

2.31 "Initial Term" has the meaning set forth in Section 13.1.

2.32 "Intellectual Property" means, collectively, Patents, Marks, copyrights, Know-How, and any other intellectual property owned or licensed by a Party.

2.33 "Kilo" means a kilogram of manufactured Active Pharmaceutical Ingredient, using a non-corrected, total, as-is weight.

2.34 "Know-How" means all non-patented and proprietary: information, inventions, developments, techniques, materials, processes, manufactures, compositions of matter or methods of use and trade secrets, whether or not patentable or copyrightable. Know-How excludes (i) Patents and (ii) any of the foregoing which would be excluded from the definition of Proprietary Information under Section 5 of the Confidentiality Agreement.

2.35 "Latent Defect" means (a) a failure of the Product to meet the Specification, or (b) Agilent's failure to manufacture the Product in accordance with cGMP, which failure or defect is (x) present at the time of delivery to Customer's carrier; (y) non-obvious and not reasonably susceptible to discovery upon receipt of the Product from Customer's carrier; and (z) subsequently detected by Customer. A Latent Defect excludes a failure or defect that (i) is attributable to a defect in the PEG delivered to Agilent by Customer for use in the Product, provided that such defect in the PEG was not discoverable by Agilent in the course of testing in accordance with Agilent's Standard Operating Procedure and provided that such defect in the PEG is not otherwise caused by Agilent's negligence; (ii) is attributable to a fundamental chemical or stability defect in the Product and results in a change in the Product after delivery by Agilent; or (iii) is the result of further processing, storage, handling or use of the Product after delivery by Agilent.

2.36 "[**]" has the meaning set forth in Section [**].

2.37 "Long-Range Forecast" has the meaning set forth in Section 4.1.3.

2.38 "Manufacturing Services" means services, other than testing and other services that are performed as part of the manufacture and supply of Product, set forth in a Statement of Work to be performed by Agilent with respect to Product and Finished Product, including stability testing.

2.39 "Manufacturing Standards" has the meaning set forth in Section 5.3.

2.40 "Marks" means the trademarks, service marks, trade dress, trade names, logos, insignia, symbols, designs or other marks identifying either Party or its products.

2.41 "Master Batch Record" has the meaning set forth in the Quality Agreement.

2.42 "Minimum Yield Requirement" means: (i) for the [**] Process, [**] of Product; and (ii) for the [**] Process, there is no applicable minimum yield requirement until mutually agreed by the Parties in writing. Upon completion of scale-up activities and [**] PPQ Batches for the [**] Process, the Parties agree to discuss in good faith a minimum yield requirement for such Process and if so agreed, the Parties will amend this Agreement (including supply deficiency terms) appropriately.

2.43 "New Customer IP" has the meaning set forth in Section 9.2.1.

2.44 "Non-Binding Forecast" has the meaning set forth in Section 4.1.2.

2.45 "Patents" means patents, patent applications and any divisions, continuations, continuations-in-part, re-issues, re-examinations, renewals or extensions thereof and any foreign counterpart of any of such U.S. patent rights.

2.46 "PEG" has the meaning set forth in Section 3.2.

2.47 "Person" means any individual, partnership, corporation, limited liability company, unincorporated organization or association, any trust or any other business entity.

2.48 "Process" has the meaning set forth in Section 9.2.2.

2.49 "Product" means the Aptamer described in Exhibit A and intermediates thereof.

2.50 "Proprietary Information" has the meaning set forth in Section 14.1.

2.51 "Purchase Order" means a written purchase order, in substantially the form agreed in good faith based on customary arrangements in the biotechnology industry, between Agilent and Customer, to be delivered by Customer to Agilent for the manufacture and supply of Product (including testing and other services performed as part of the manufacture and supply of Product) pursuant to this Agreement.

2.52 "Quality Agreement" means the agreement by and between Agilent and Customer, executed by duly authorized representatives of each Party, setting forth the obligations of the Parties with respect to quality matters applicable to the commercial manufacturing and supply of the Product and Customer's drug product testing under this Agreement.

2.53 "Quarter" means a three (3) month period of each calendar year beginning, as applicable, January 1, April 1, July 1 or October 1.

2.54 "Quarterly Product Batch Maximum" means (i) for the [**] Process, [**] Batches or (ii) for the anticipated [**] Process, [**] Batches.

2.55 "Regulatory Approval" means any approval, notice, permit, license, consent, or similar requirements of any Regulatory Authority that are necessary for Customer's commercial manufacture, distribution, and sale of the Finished Product.

2.56 "Regulatory Authority" has the meaning set forth in the Quality Agreement.

2.57 "Renewal Term" has the meaning set forth in Section 13.1.

2.58 "Rolling Forecast" has the meaning set forth in Section 4.1.

2.59 "[**]" has the meaning set forth in Section [**].

2.60 "Specification" means the specification for the Product as set forth in Exhibit F, which specification may be amended from time to time in accordance with this Agreement.

2.61 "Statement of Work" means any statement of work as mutually agreed to by the Parties for the performance of Manufacturing Services under this Agreement.

2.62 "Supply Deficiency" has the meaning set forth in Section 4.11.1.

2.63 "Supply Failure" has the meaning set forth in Section 4.11.1.

2.64 "Target" means a protein, cytokine, enzyme, receptor, transducer, transcription factor, antigen or any other non-nucleic acid molecule.

2.65 "Term" has the meaning set forth in Section 13.1.

2.66 "Third Party" means any Person who is not a Party or an Affiliate of a Party.

3. OBLIGATIONS OF THE PARTIES; STATEMENTS OF WORK

3.1 Obligations of Agilent. Agilent will manufacture and supply the Product to Customer and perform the Manufacturing Services at the Facility in accordance with the terms of this Agreement, the Quality Agreement, any applicable Purchase Order or Statement of Work and in accordance with cGMP and all laws and regulations applicable to the manufacture and supply of the Product at the Facility and the performance of the Manufacturing Services. Agilent shall perform any testing and other services performed as part of the manufacture and supply of Product as well as the Manufacturing Services in a professional and workmanlike manner consistent with industry standards. Agilent will deliver the Product in accordance with the delivery dates set forth in each accepted Purchase Order and will perform the Manufacturing Services in accordance with the delivery dates and other terms set forth in each applicable Statement of Work.

3.2 Obligations of Customer. Customer will provide Agilent with polyethylene glycol ("PEG") in accordance with Section 3.3 and information and cooperation reasonably necessary for the manufacture and supply of the Product in accordance with this Agreement and the Quality Agreement.

3.3 PEG.

3.3.1 Initially during the Term, Customer will be responsible for the supply of PEG in sufficient amounts to enable Agilent to manufacture Product ordered by Customer hereunder. During the Term, the Parties will work together towards the goal of transitioning responsibility for the supply of PEG to Agilent, and with such transition, amend the Sections of this Agreement pertaining to PEG supply and the pricing for the Product accordingly, it being understood that factors outside of Agilent's control (including the willingness of a PEG supplier to contract with Agilent) may affect Agilent's ability to assume responsibility for the supply of PEG, and that any failure to do so shall not be considered a breach of this Agreement. While Customer is responsible for supply of PEG, the remaining provisions of Section 3.3 shall apply until they are so amended.

3.3.2 Starting [**] and during the Term, Customer shall use commercially reasonable efforts to maintain a sufficient safety stock of PEG necessary for Agilent to manufacture the quantity of Product in the Binding Forecast over the next [**]; however, not maintaining such safety stock will not be, on its own, a breach of Customer's obligations under this Agreement. If Customer does not maintain a sufficient safety stock of PEG or otherwise does not deliver PEG in sufficient amounts and by the required delivery dates to enable Agilent to manufacture any applicable Batch, including any Batch that Agilent manufactures to address a Supply Deficiency, such Batch shall be deemed to be cancelled by Customer and subject to the cancellation fees in Section 4.7.

3.3.3 Customer shall deliver sufficient amounts of PEG to Agilent at least [**] but no more than [**] prior to the scheduled commencement of manufacture for the applicable Product. Customer shall use commercially reasonable efforts to enter into an agreement with [**] for supply of the PEG (the "PEG Supply Agreement"), or if and when Customer chooses, with another Third Party to obtain supply of PEG for the Product. For purposes of clarity, Customer may terminate the PEG Supply Agreement with [**]; provided that Customer has obtained an alternative source of supply of PEG. Notwithstanding any other provision herein, Agilent shall not be liable for any delays or supply failures associated with (i) Customer's failure to supply PEG in sufficient amounts and by the required delivery dates to enable Agilent to manufacture Product ordered by Customer or (ii) termination of Customer's PEG Supply Agreement with [**] and

retention of an alternative source of supply of PEG. Customer shall reimburse Agilent for any reasonable direct costs incurred by Agilent to qualify any alternative source of supply of PEG. Customer shall immediately notify Agilent in writing if Customer reasonably anticipates any delay or shortfall in the supply of PEG in sufficient amounts to enable Agilent to manufacture Product ordered by Customer hereunder. In the event of cancellation or deferment of any Purchase Order due to Customer's failure to supply sufficient amounts of PEG to enable Agilent to manufacture Product ordered by Customer hereunder, the cancellation fees set forth in Section 4.7 shall apply.

3.3.4 PEG delivered shall be held by Agilent on behalf of Customer on the terms and conditions contained in this Agreement and in accordance with any mutually agreeable instructions provided by Customer (it being understood that Agilent shall be deemed to have agreed to any written instruction provided to Agilent regarding the handling of PEG if it has not objected to such instruction upon delivery of the PEG to Agilent). Customer shall maintain insurance for the PEG supplied by Customer with customary and adequate coverage amounts to cover damage to and risk of loss of PEG while at Agilent's facility, using reputable national insurance carriers. Customer shall provide any such written instructions to Agilent at least [**] prior to delivery of the PEG. Upon receipt of the PEG, Agilent will promptly do a visual inspection of the PEG container to ensure it has not been compromised. Agilent will, promptly, but in no event later than [**] of receiving the PEG, notify Customer in writing in accordance with the Quality Agreement in the event that such visual inspection revealed that the PEG was compromised at the time of delivery or was, at the time of delivery, otherwise unusable to manufacture Product. Agilent will conduct raw material release testing of the PEG in accordance with the specification for the PEG consistent with the Quality Agreement. Agilent will provide Customer notice in writing in accordance with the Quality Agreement in the event that the PEG does not comply with the specification for the PEG. In the event that Agilent provides a notification in accordance with this Section 3.3.4, Agilent shall not be liable for any delays or supply failures associated with delivered PEG that, at the time of delivery, was compromised or, at the time of delivery, was otherwise unusable to manufacture Product ordered by Customer hereunder. Agilent acknowledges that all PEG delivered shall remain the property of Customer and Agilent shall clearly identify all such PEG in storage and in its books as goods belonging to Customer. Agilent shall not use any such PEG for any purpose other than for Customer under this Agreement. Agilent shall use first in – first out and first expiry – first out methods of usage and endeavor to use a minimum reasonable amount of PEG necessary to manufacture the Product (it being acknowledged and understood that due to PEG handling and other manufacturing practicalities, it is not possible for Agilent to use [**] percent ([**]%) of the PEG provided to Agilent in manufacturing of the Product).

3.3.5 Subsequent to the completion of the validation Batches for the New Drug Application submission for the Finished Product, Agilent shall credit Customer for [**] percent ([**]%) of the invoiced cost of any PEG (which in no event shall be greater than $[**] per Kilo) and any associated freight fees and taxes in the event that such PEG cannot be used in the Processing of the Product as a result [**]. Agilent shall immediately inform Customer of any loss or damage to the PEG and promptly provide in writing all explanations and evidence relating thereto.

3.3.6 Subsequent to the completion of the validation Batches for the New Drug Application submission for the Finished Product, Agilent shall [**] (i) [**]; (ii) [**]; (iii) [**]; or (v) [**], provided that [**] of this Section 3.3.6. For the purposes of [**] under this Section 3.3.6, the Parties agree that the [**] under this Section 3.3.6 shall be [**] with respect to [**] (a) [**]; (b) [**]; (c) [**]; and (d) [**] under this Section 3.3.6 for [**] as described in subsection (v) above shall be determined as follows: (w) [**]; (x) [**]; (y) [**]; and (z) [**].

3.3.7 Agilent shall maintain up-to-date records of all PEG held in inventory and, within the [**] or at such other frequency as the Parties may agree, shall provide to Customer a complete and accurate list of all PEG held by it on the [**]. Such inventory list shall in particular specify the inventory balance of PEG at the relevant date. Agilent shall also provide Customer with written reports on a [**] basis reconciling the quantities of the

PEG provided to and held by Agilent, the consumption of the PEG and the estimated yield losses in the Processing.

3.3.8 In addition to the reports set forth in Section 3.3.7, Agilent shall provide to Customer the result of an inventory count to be carried out, under the joint supervision of Agilent and Customer, in accordance with Agilent's usual year end audit procedures, of all the PEG held by Agilent as of [**] (or such other date as the Parties may agree) of each calendar year, such report to be delivered on or before [**] after such date, or within such other time as the Parties may agree. Agilent shall be responsible for all discrepancies (such as, for example, missing quantities) not accounted for during such yearly inventory count or in connection with the monthly inventory report without regard to the reason for the discrepancy. Each Party shall pay for its own fees under this Section.

3.4 Statements of Work.

3.4.1 During the Term, Customer may request that Agilent perform Manufacturing Services. As mutually agreed by the Parties in a Statement of Work, each Party shall perform the obligations set forth in each Statement of Work. In the event of any inconsistency between this Agreement and a Statement of Work, the terms and conditions of this Agreement shall prevail, subject to the terms of Section 16(j). Agilent shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform such obligations in accordance with this Agreement and any applicable Statement of Work.

3.4.2 Customer may propose changes to a Statement of Work (other than cancellation or deferment) at any time by a written request. Agilent shall consider all such requests in good faith and notify Customer within [**] of its receipt of such request of any proposed modifications to the price or delivery dates incurred as a direct result of the change. Upon Customer’s written acceptance of such proposal, the Statement of Work shall be deemed so modified.

3.5 Exclusivity; Minimum Purchase Obligation.

3.5.1 Subject to the following sentence, Agilent and its Affiliates will only supply Anti-[**] Aptamers or Finished Product to Customer and any Affiliate of Customer or Third Party designated by Customer during the Term and for the following periods after the Term: (a) if Agilent terminates this Agreement at the end of the Initial Term by giving notice of intent not to renew pursuant to Section 13.1, for a [**] period after the Term; (b) if Agilent terminates this Agreement at the end of the first Renewal Term by giving notice of intent not to renew pursuant to Section 13.1, for a [**] period after the Term; (c) if Customer terminates this Agreement at the end of the Initial Term or at the end of any Renewal Term by giving notice of intent not to renew pursuant to Section 13.1, for [**] period after the Term; (d) if Agilent terminates this Agreement pursuant to Sections 13.2(a) or 13.2(b) (whether during the Initial Term or any Renewal Term), for no additional period after the Term; (e) if Customer terminates this Agreement pursuant to Sections 13.2(a), 13.2(b), or 13.2(e) during the Initial Term, until the later of seven (7) years from the date of Regulatory Approval in the United States of a New Drug Application for the Finished Product or for a [**] period after the Term; (f) if Customer terminates this Agreement pursuant to Sections 13.2(a), 13.2(b), or 13.2(e) during the first or second Renewal Term, for a [**] period after the Term; (g) if Customer terminates this Agreement pursuant to Section 13.2(d), for [**] period after the Term; and (h) if Agilent terminates this Agreement after the second Renewal Term by giving notice of intent not to renew pursuant to Section 13.1, or if Customer terminates this Agreement pursuant to Sections 13.2(a), 13.2(b) or 13.2(e) during a third or subsequent Renewal Term, for a [**] period after the Term (collectively, as applicable, the “Exclusivity Period”). During the Term, the Exclusivity Period shall terminate at the end of a calendar year if Customer has not purchased a minimum of [**] of Product using the [**] Process or larger process scale (or an equivalent number of Batches using the [**] Process, which for purposes of this sentence, [**] Process Batches are deemed equivalent to one [**] Process Batch) in such calendar year, and if Customer has not purchased such minimum amount, Customer may elect to maintain the Exclusivity Period in accordance with this Section 3.5.1, at Customer’s sole discretion, by paying Agilent $[**] no later than [**] after the end of such calendar year. Agilent and

Customer agree that if the Exclusivity Period terminates pursuant to the prior sentence such termination does not by itself affect the Parties' obligations elsewhere in the Agreement or the continued effectiveness of this Agreement.

3.5.2 Customer agrees that during the Term, Agilent shall be Customer's supplier of at least [**] percent ([**]%) of Customer's commercial manufacturing requirements of Product on an annual basis for use in the United States and any additional future jurisdictions as mutually agreed to by the Parties in writing, or such lesser amount in the event Agilent is unable to supply such [**]%) percent. If Customer does not order sufficient Product to meet such purchase requirement for any such calendar year during the Term, Customer shall have the right to cure such deficiency by ordering the missing quantity of Product during the [**] period following the end of such calendar year. Provided that Customer has cured such deficiency by ordering the missing quantity of Product during the [**] period following the end of such calendar year, such deficiency shall not be deemed a breach of this Agreement and Agilent shall not have the right to terminate this Agreement as a result of such deficiency. Upon [**] prior written notice to Customer, Agilent may, at its own expense, appoint an independent auditor to audit and examine Customer's books and records solely for the purpose of confirming Customer's compliance with the minimum purchase obligation in this Section 3.5.2, and such audit may be made no more than [**].

4. SUPPLY

4.1 Forecasts. During the Term of this Agreement, Customer shall submit to Agilent's designated representative a written rolling forecast based on the quarter the manufacture of Batches will start. Each written rolling forecast will include the quantity of Product described in Kilos and in number of Batches which Customer expects to order from Agilent using the [**] Process and the [**] Process (and any other process scale mutually agreed by the Parties) during the next [**] Quarters (the "Rolling Forecast"). The first Rolling Forecast, as mutually agreed by the Parties, is attached hereto in Exhibit B. Thereafter, on or before the first day of each Quarter during the Term, Customer shall submit a revised Rolling Forecast covering such Quarter and the following [**] Quarters, in accordance with this Section 4.1. Each Rolling Forecast consists of a Binding Forecast and Non-Binding Forecast as described below.

4.1.1 Binding Forecast. The first [**] Quarters of each Rolling Forecast shall constitute a binding order for the quantity of Product specified in those [**] Quarters (together with any Quarters made binding pursuant to Section 4.1.2.1, the "Binding Forecast"). Customer shall submit the Binding Forecast for each Rolling Forecast subject to the following limitations: (a) the quantity of Product, described in Kilos and in number of Batches, forecast to be manufactured using the [**] Process and the [**] Process for Quarters [**] through [**] must match the quantity of Product forecast for Quarters [**] through [**] of the prior Quarter's Rolling Forecast; (b) for each process scale, if not prohibited by Section 4.1.2.1, the quantity of Product forecast for the [**] Quarter of the Rolling Forecast may only increase by up to [**] percent ([**]%) or decrease by up to [**] percent ([**]%) relative to the quantity of Product forecast for the [**] Quarter of the prior Quarter's Rolling Forecast, unless such [**] Quarter of the prior Quarter's Rolling Forecast has been made binding pursuant to Section 4.1.2.1, in which case the quantity of Product forecast for such [**] Quarter will be equal to the [**] Quarter of the prior Quarter's Rolling Forecast; (c) for the [**] Process, the total number of Batches forecast in any given calendar year cannot exceed [**] Batches; (d) for each process scale, the number of Batches forecast in any given Quarter cannot exceed the Quarterly Product Batch Maximum for that process scale; (e) the forecast quantity of Product in Kilos for each process scale for the Quarter must be a multiple of the estimated quantity of Product to be manufactured in one Batch for that process scale (*i.e.*, forecasted quantities cannot be based on manufacture of partial Batches of Products); and (f) any increases in quantity of Product for any given Quarter relative to the forecast for such Quarter in the prior Quarter's Rolling Forecast are subject to the availability of raw materials required for the manufacture of Product.

4.1.2 Non-Binding Forecast. Quarters [**] through [**] of each Rolling Forecast (the "Non-Binding Forecast") are non-binding except as set forth in Section 4.1.2.1 but are subject

to the limitations set forth in this Section 4.1.2. Customer shall submit the Non-Binding Forecast for each Rolling Forecast subject to the following limitations: (a) the amount of Product forecast by Customer for each process scale and for each Quarter of the Non-Binding Forecast shall constitute Customer's good-faith estimate of the amount of Product required by Customer for each such Quarter; (b) for each process scale, if not prohibited by Section 4.1.2.1, the quantity of Product forecast for the [**] through [**] Quarters of the Rolling Forecast may only increase by up to [**] percent ([**]%) or decrease by up to [**] percent ([**]%) relative to the amount forecast for such Quarter in the prior Quarter's Rolling Forecast (*i.e.*, the [**] through [**] Quarters of the prior Quarter's Rolling Forecast, as applicable), unless such Quarter in the prior Quarter's Rolling Forecast has been made binding pursuant to Section 4.1.2.1, in which case the quantity of Product forecast for such Quarter in the then-current Quarter's Rolling Forecast will be equal to such Quarter in the prior Quarter's Rolling Forecast; (c) for the [**] Process, the total number of Batches forecast in any given calendar year cannot exceed [**] Batches; (d) for each process scale, the number of Batches forecast in any given Quarter cannot exceed the Quarterly Product Batch Maximum for that process scale; (e) the forecast quantity of Product in Kilos for each process scale for the Quarter must be a multiple of the estimated quantity of Product to be manufactured in one Batch for that process scale (*i.e.*, forecasted quantities cannot be based on manufacture of partial Batches of Products); and (f) any increases in quantity of Product for any given Quarter relative to the forecast for such Quarter in the prior Quarter's Rolling Forecast are subject to the availability of raw materials required for the manufacture of Product.

4.1.2.1 Right of First Refusal for Additional Quarters. At any time during the Term, if another customer of Agilent indicates willingness to reserve any manufacturing capacity during the [**] or [**] Quarters of the then-current Quarter's Rolling Forecast, Agilent will submit a written request to Customer asking Customer to commit to converting some or all Batches forecast by Customer for such [**] or [**] Quarters to become binding. If Customer wishes to so commit, it shall respond in writing to Agilent within [**] of Agilent's request that such Batches shall be deemed part of the Binding Forecast, and shall submit to Agilent Purchase Orders corresponding to such Batches within [**] of Customer's writing in accordance with the last sentence of Section 4.2.1, and Agilent may not allocate such capacity to such other customer. If Customer responds in writing that it does not wish to so commit, or it does not respond in writing or submit Purchase Orders within the applicable periods, Customer's Rolling Forecast for such [**] and/or [**] Quarters (as applicable) shall be deemed decreased by the amounts of such Batches, Customer may not increase the Product forecast for such Quarters for the remainder of the Rolling Forecast, and Agilent may allocate such capacity to any other customer; provided that, if such capacity later becomes available, Agilent will use commercially reasonable efforts to notify Customer and provide Customer such capacity.

4.1.3 Long-Range Forecast. In addition to the Rolling Forecast, Customer shall submit to Agilent on or before [**] of each calendar year during the Term, a good-faith, non-binding, written, rolling forecast of the quantity of Product, described in Kilos and in number of Batches, which Customer expects to order from Agilent for delivery using the [**] Process and the [**] Process (and any other process scale mutually agreed by the Parties) during the following two periods relative to the time of such forecast: (a) Quarters [**] through [**] and (b) Quarters [**] through [**] (the "Long-Range Forecast").

4.1.4 Acceptance of Forecasts. With Customer's submission of each Rolling Forecast, Customer shall conspicuously identify in writing any portion of the Rolling Forecast that does not comply with the requirements of this Agreement for such Rolling Forecast. Thereafter, Agilent shall notify Customer within [**] from receipt whether Agilent accepts or rejects such Rolling Forecast (if Agilent fails to notify Customer within that period, such Rolling Forecast is deemed to be accepted). If Agilent rejects a Rolling Forecast or any portion of such Rolling Forecast exceeds the Quarterly Product Batch Maximum or any other limitation on such Rolling Forecast, Agilent and Customer shall

discuss in good faith how Agilent can meet Customer's needs and Agilent will use commercially reasonable efforts to do so. Upon written agreement by the Parties for the amounts requested in any such Rolling Forecast, such Rolling Forecast shall be deemed to be accepted.

4.2 Purchase Orders.

4.2.1 Purchase Order Submission. Within [**] of the Effective Date of this Agreement, Customer shall submit to Agilent one Purchase Order for each Batch of Product comprising the quantities of Product forecast for the first [**] Quarters of the Binding Forecast, with the dollar amount of each such Purchase Order corresponding to the cost of the Batch as described in Section 6.1; provided that to the extent any such quantities have already been submitted in Purchase Orders by Customer before the Effective Date, those quantities do not need to be included in the initial Purchase Order hereunder. Thereafter, on or before the [**] of each Quarter during the Term, in conjunction with each Rolling Forecast to be submitted, Customer shall submit to Agilent additional Purchase Orders for each Batch of Product comprising the quantities of Product forecast for the [**] Quarter of the Rolling Forecast, unless Customer has already submitted such Purchase Orders pursuant to Section 4.1.2.1. Each Purchase Order shall specify the applicable process scale, the Quarter for start of manufacture, and the manner and address of delivery, all of which shall be subject to this Article 4.

4.2.2 Acceptance of Purchase Orders. Agilent shall notify Customer as to whether any Purchase Order delivered pursuant to Sections 4.2.1 or 4.1.2.1 has been accepted or rejected within [**] following Agilent's receipt of such Purchase Order, unless such Purchase Order exceeds Customer's then current credit limit, in which case the [**] period shall be extended to [**]. Customer's credit limit shall be reviewed by Agilent consistent with Agilent's corporate policy, and adjusted as necessary, no more than [**] or upon any material change specific to Customer that would affect Customer's ability to perform its obligations hereunder, and with each adjustment, Agilent shall notify Customer. Agilent may only reject a Purchase Order as follows: (i) the Purchase Order is not in compliance with this Agreement; (ii) the Purchase Order does not have a delivery address; or (iii) the Purchase Order does not comply with Agilent's credit limit standards; provided that if Customer agrees to make an up-front pre-payment representing all or a portion of the amount due with respect to such Purchase Order as may be reasonably requested by Agilent, Agilent may not reject the Purchase Order on the basis that it does not comply with Agilent's credit limit standards, which pre-payment shall be refunded to Customer by Agilent in the event Agilent fails to deliver Product for which the pre-payment was made. In the event that Agilent rejects a Purchase Order hereunder, Agilent shall notify Customer in writing within the [**] period or [**] period, as applicable, of the reasons why such Purchase Order was rejected by Agilent. Agilent's failure to affirmatively reject a Purchase Order that meets the requirement of this Agreement within the applicable time limit will be deemed an acceptance of such Purchase Order. Customer may, at its option and within [**] after any such rejection, submit a revised Purchase Order.

4.2.3 Fulfillment of Purchase Orders. Upon acceptance of a Purchase Order by Agilent, Agilent commits to deliver the applicable quantity of Product during the applicable Quarter of such Purchase Order. The Parties acknowledge and agree that Agilent may deliver Product up to [**] prior to and no later than [**] after the applicable delivery date set forth in the applicable Purchase Order.

4.3 Advance Payments. Following acceptance of each applicable Purchase Order, Agilent may invoice Customer against such Purchase Order as follows: (a) an amount equaling [**] percent ([**]%) of the price of each applicable Batch at [**] prior to the start of manufacture of such Batch; and (b) an amount equaling [**] percent ([**]%) of the price of each applicable Batch at [**] prior to the start of manufacture of such Batch. Customer shall pay such invoices in accordance with Section 6.2. Agilent may revise such advance payment percentage based on changes to Customer's credit limit as specified in Section 4.2.2. Agilent shall notify Customer in writing of any such changes to the advance payment percentage.

4.4 Delivery and Acceptance. Subject to Section 8.2.2, Agilent will deliver the Product to the carrier selected by Customer. Shipment terms are EXW Agilent's Facility (Incoterms 2020). Title and

risk of loss will pass to Customer when the Product is delivered to Customer's carrier. Customer is responsible for payment of all shipment costs, including any insurance necessary to guard against loss or damage during shipment. Acceptance shall occur upon delivery of the Product to Customer's carrier. Upon shipment of Product, Agilent may invoice Customer for such Product against the Purchase Order for the Batch applicable to such Product (less any pre-paid amounts for such Product) and Customer shall pay such invoices in accordance with Section 6.2.

4.5 Certificates. An appropriate Certificate of Analysis (which shall include a material safety data sheet) and Certificate of Compliance shall be provided with the shipment of each Batch delivered to Customer.

4.6 Shipping Instructions. Customer will provide Agilent with packaging and shipping instructions including temperature requirements, temperature monitoring instructions and packaging specifications at the time it submits the applicable Purchase Order. Absent such instructions from Customer, Agilent shall package, label and ship the Product using Agilent's standard shipping, packaging and procedures. Notwithstanding any other provision of this Agreement, Agilent will not be liable for any loss or damage caused by Agilent's compliance with Customer's packaging and shipping instructions or Customer's failure to provide packaging and shipping instructions or any loss or damage caused by Customer's carrier.

4.7 Cancellation of Purchase Orders. Customer may cancel manufacture of Product under any Purchase Order or part thereof by providing Agilent with written notice thereof prior to the scheduled delivery date. For the avoidance of doubt, delivery dates for Product may not be deferred; any notice of deferment shall be deemed a notice of cancellation unless Agilent agrees otherwise as set forth in Section 4.8, which it shall have the right to decide in its sole discretion. Subject to Article 12 and the final sentence of this Section 4.7, upon cancellation of manufacture of Product that constitutes any part of a Binding Forecast, whether by Customer's written notification or by Customer's failure to supply sufficient quantities of PEG, if applicable, Agilent shall invoice Customer against the applicable Purchase Order for the applicable Batch(es) for an amount equal to the full amounts payable for such cancelled Product, less (a) any advance payments or other amounts previously paid by Customer applicable to such cancelled Product and (b) any raw material or pass-through costs applicable to such cancelled Product not yet incurred by Agilent. Customer shall pay such invoices in accordance with Section 6.2. However, in the event that Agilent is able to use any raw material purchased under a cancelled Purchase Order for another Purchase Order of Customer or for another customer within [**] after the date of the scheduled commencement for manufacture of the cancelled Batch(es), Agilent will issue a credit to Customer for the cost of such raw materials which Customer may apply to any future unpaid invoices. Notwithstanding anything to the contrary herein, if Agilent is unsuccessful with scale up activities for the [**] Process as set forth in the Project Proposal dated [**] for the [**] for Customer and Customer cancels GMP manufacture activities in accordance with such Project Proposal, then the Batches and related stability studies ordered by Customer for the [**] Process (including the Batches set forth in such Project Proposal and any other Batches under Binding Forecast or ordered by Customer at such scale under this Agreement) are deemed to be cancelled without any additional fee or penalty and Agilent shall refund Customer all advance payments made by Customer for such Batches and related stability studies, less any amounts for costs incurred by Agilent prior to the effective date of cancellation.

4.8 Deferments of Purchase Orders. If Customer wishes to defer manufacture or delivery of any Purchase Order or part thereof, Customer shall provide Agilent with written notice thereof with as much notice as practical prior to the scheduled delivery date. Agilent will review any request for deferment in good faith, but shall not be obligated to agree to any deferment. Agilent may request a reasonable deferment fee as a condition of agreeing to defer delivery of any Purchase Order or part thereof if such deferment would materially impact Agilent's manufacturing obligations to any other customer.

4.9 Safety Stock.

4.9.1 Agilent shall maintain a sufficient inventory level of critical raw materials and supplies ("Safety Stock") required for Agilent to manufacture and supply the Product for Customer based upon the then-current Binding Forecast. The Safety Stock will not include the PEG while Customer is responsible for procuring the PEG, but will include the PEG if and when Agilent assumes responsibility for procuring the PEG pursuant to Section 3.3. Upon Customer's reasonable request and no more than [**], Agilent shall

provide assurances that it maintains sufficient Safety Stock required for Agilent to manufacture and supply the Product for Customer.

4.9.2 Agilent will use commercially reasonable efforts to manage and use the Safety Stock in a manner that minimizes the risk that any amount of the Safety Stock expires before it can be used to manufacture Product hereunder, including, but not limited to, using the Safety Stock on a first in, first out basis.

4.9.3 Agilent shall at all times retain title to the Safety Stock and assumes the risk of loss of any or all of such Safety Stock. In the event any or all of the Safety Stock is damaged or destroyed, Agilent shall, [**], replace the damaged or destroyed Safety Stock with replacement raw materials of similar type and quality.

4.10 Notification of Shortage of Supply. Agilent shall notify Customer immediately upon becoming aware of an event of force majeure under Article 12 or any other event, including shortage of or inability to procure raw materials or supplies of the Safety Stock, that would render Agilent unable to supply any quantity of the Product required to be supplied hereunder (such event, an "Agilent Supply Interruption"). Agilent will use commercially reasonable efforts to provide Customer with as much advance notice as reasonably practicable.

4.11 Supply Deficiency; Supply Failure.

4.11.1 Definitions of Supply Deficiency; Supply Failure. A "Supply Deficiency" means Agilent has delivered less than [**] percent ([**]%) of the Minimum Yield Requirement for any Batch(es) of Product that are priced on a per-Batch basis (*i.e.*, Batches that are not priced on a per-gram basis) that are specified in any accepted Purchase Order in accordance with the delivery date set forth therein and this Agreement (the undelivered amount (i.e., the difference of the Minimum Yield Requirement for such Batch subtracted by the actual delivered amount) being referred to herein as the "Deficiency Amount"), unless such failure results from a delay or default by Customer under the Agreement (including but not limited to a failure to supply sufficient amounts of PEG to enable Agilent to manufacture Product ordered by Customer hereunder, if applicable). A "Supply Failure" means Agilent has failed to cure a Supply Deficiency by (i) [**], and (ii) if the Deficiency Amount is greater than or equal to [**] percent ([**]%) of the Minimum Yield Requirement, Agilent shall use [**] the Minimum Yield Requirement). If the Deficiency Amount is less than [**] percent ([**]%) of the Minimum Yield Requirement, Agilent will [**], depending on [**], subject to [**]. For the avoidance of doubt, a shortfall where Agilent has delivered [**]% or more of the Minimum Yield Requirement for the Batch(es) of Product specified in any accepted Purchase Order in accordance with the delivery date set forth therein shall not constitute a Supply Deficiency.

4.11.2 Procedure to Address Supply Deficiency. In the event of a Supply Deficiency where Agilent is not obligated to take the steps described in Section 4.11.1(ii), Agilent will use commercially reasonable efforts to take one (1) or more of the following steps, as mutually agreed with Customer, in the following order of preference whenever practicable (i.e., with highest preference given to the remedy in (a) and the lowest preference given to the remedy in (d)): (a) [**].

4.11.3 Alternative Supply for Supply Failure or Agilent Supply Interruption. In the event of a Supply Failure or an Agilent Supply Interruption, notwithstanding the minimum purchase provisions set forth in Sections 3.5.1 and 3.5.2 or Binding Forecasts or Purchase Orders submitted pursuant to Sections 4.1.1 and 4.2.1, Customer will have the right to purchase from one or more alternative suppliers all of its Product requirements, provided that Customer will use commercially reasonable efforts to limit any order of Product with alternative suppliers to the extent of and for the anticipated duration of the Supply Failure or Agilent Supply Interruption. Customer will resume purchase of its Product requirements under Sections 3.5.1 and 3.5.2 from Agilent as soon as (a) Agilent reasonably demonstrates that Agilent is able to resume supplying Product to fulfill Customer's requirements and (b) Customer has fulfilled all obligations or commitments, if any, undertaken by Customer in connection with Customer's arrangement(s) with the alternative supplier(s). For avoidance of doubt, any purchases of Product by Customer from an alternative supplier during a Supply Failure or Agilent Supply Interruption will, in addition to Customer's purchases from Agilent under this Agreement, count towards

the [**] and [**] percent ([**]%) purchase commitments from Agilent under Sections 3.5.1 and 3.5.2 and the Binding Forecasts and Purchase Orders submitted pursuant to Sections 4.1.1 and 4.2.1.

4.11.4 Technology Transfer. In the event of (i) a Supply Failure, (ii) an Agilent Supply Interruption lasting or is reasonably expected to last longer than [**], or (iii) termination of this Agreement by Customer pursuant to Sections 13.2(a) or (b), and provided that Customer does not then have a validated and approved alternative supplier of Product, Agilent and its Affiliates shall use their best efforts to co-operate, and cause their approved subcontractors to co-operate, in good faith and in accordance with a technology transfer plan to be agreed in good faith with Customer, to provide a general, high-level description of the Process used to manufacture and supply the Product to an alternative supplier(s) of Product as further specified in this Section. For the sake of clarity, the licenses granted in Sections 9.3.2.1 and 9.3.2.2 shall survive and remain in full force and effect. Agilent shall transfer to Customer or its designee the technology and materials agreed upon by the Parties in the technology transfer plan; however, Agilent shall not be required to disclose any of its trade secrets comprising the Process. As agreed upon by the Parties in the technology transfer plan, Agilent shall transfer to Customer or its designee any Safety Stock that is specific to Customer, and Customer shall pay Agilent an amount equal to the cost of the inventory of such Safety Stock. Agilent shall further provide the necessary technical assistance and required documentation necessary for transferring such development, manufacture and supply responsibilities to an alternative supplier(s) as agreed upon by the Parties in the technology transfer plan. If applicable and to the extent requested by Customer and permitted thereunder, Agilent shall assign to (or if assignment is not practicable, then grant licenses to) Customer or its designee any Third Party agreements to which Agilent or any of its Affiliates is a party that relate solely to the development, manufacture and supply of the Product. In addition, Agilent will also reasonably assist Customer or its designee in obtaining other items necessary for the development, manufacture and supply of the Product. Agilent and its Affiliates and subcontractors shall be responsible for their costs and expenses in connection with this Section 4.11.4.

5. PROCESSING OF PRODUCT

5.1 Storage and Handling. Agilent shall store and handle the raw materials (including PEG), consumables and packaging components under appropriate conditions and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of such materials and components. Agilent shall store and handle the Product in accordance with the Specification and under appropriate conditions as defined by Customer in accordance with the Product stability studies and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of the Product.

5.2 Inventory Control. Agilent shall provide Customer with [**] inventory reports [**], which reports shall include [**].

5.3 Manufacturing Standards. Agilent shall manufacture the Product in conformity with the Process, Master Batch Record, cGMP, the Quality Agreement and the Specification (the "Manufacturing Standards").

5.4 Process Changes or Improvements. The Parties shall collaborate in good faith to evaluate and implement potential process improvements to increase Processing efficiencies and Agilent Product capacity, including any potential improvements to meet Agilent's and Customer's sustainability goals. Agilent agrees that no change to the Process shall be made without the prior written approval of Customer. Notwithstanding the foregoing, any such change to the Process shall be subject to the agreed upon Change Management process as set forth in the Quality Agreement and the prior mutual agreement of the Parties with respect to the costs and expenses associated with the agreed upon change.

5.5 Business Continuity Plan. Agilent shall maintain a business continuity plan intended to safeguard Agilent's continued performance of its obligations under this Agreement. Such business continuity plan is the Proprietary Information of Agilent. [**].

6. PRICE AND PAYMENT

6.1 Pricing. The price for manufactured Product shall be as set forth in each Purchase Order based on the pricing for Product set forth in Exhibit E except: (a) to the extent that the Manufacturing Standards as of the Effective Date for Product ordered are materially modified pursuant to the Change Management provisions set forth in the Quality Agreement, including as a result of Agilent taking responsibility for procurement of the PEG pursuant to Section 3.3, the Product pricing may be modified; provided that any increase in pricing shall be proportionate to the increase in Agilent's costs to manufacture Product based on such modified Manufacturing Standards and (b) pricing for Product set forth in Exhibit E will only be valid for a [**] and may reviewed [**] by the Parties on [**] as set forth in Section 6.6. Any price changes shall only apply for Purchase Orders made after the effective date of such price change. Pricing for Manufacturing Services shall be as set forth in each applicable Statement of Work.

6.2 Payment. Agilent shall invoice Customer at the time of, as applicable, shipment of the Product in accordance with this Agreement or completion of the Manufacturing Services, unless otherwise agreed to by the Parties in a Statement of Work. Payment of an undisputed invoice for Product is due [**] from the date of invoice. Payment of a disputed invoice for Product is due [**] from the date of resolution of the dispute. Payment terms are subject to change if Customer's financial condition or payment record merits such change.

6.3 Taxes. Prices are exclusive of any sales, use, service, value added or other similar taxes. Any tax, duty, custom, insurance or other fee of any nature imposed on Product or services by any federal, state, local or foreign governmental authority shall be paid by Customer. If Agilent is required to pay any such tax or fee, Customer will reimburse Agilent promptly upon invoice by Agilent. If Customer claims exemption from any taxes, Customer will provide Agilent with an appropriate exemption certificate for the delivery jurisdiction. Each Party will be responsible for its own income, employment and property taxes.

6.4 Remedies. Agilent may temporarily discontinue its performance of the manufacture and supply obligations under this Agreement if Customer fails to pay any sum when due and Customer has not cured such failure within [**] after receipt of written notice from Agilent identifying such failure.

6.5 Manufacturing Cost Reductions. The Parties will work together during the Term to identify opportunities to reduce the cost of manufacturing Product. Any such cost reductions shall be subject to Section 5.4 and the Change Management process set forth in the Quality Agreement. With respect to all other reductions in costs, including any cost reductions associated with the PEG, the Parties shall negotiate in good faith decreases to the price for the Product.

6.6 Manufacturing Cost Increases. The Parties agree that Agilent shall have, after good faith negotiations with Customer, the right to increase Product prices provided that Agilent can demonstrate that such increases are based upon unavoidable increases in material operating costs. Any increases in labor costs will cause the Parties to negotiate in good faith increases to the price of the Product, provided that such increases shall not exceed the Producer Price Index percentage as published by the United States Department of Labor Producer Price Index for Pharmaceutical and Medicine Manufacturing (Series ID: PCU32543254), or any such replacement or substitute index published by the United States government in the event the Producer Price Index for Pharmaceutical and Medicine Manufacturing is discontinued. Price increases under this Section may not be made more than [**].

7. REPRESENTATIONS AND WARRANTIES

7.1 General Representations and Warranties. Each Party represents and warrants to the other Party that (i) it has the right and authority to enter into this Agreement and to carry out its obligations hereunder; (ii) it is validly existing in each jurisdiction in which it is incorporated and is authorized to do business under the laws of each jurisdiction in which it engages in business activities; and (iii) it is not aware of any legal, contractual or other restriction, limitation or condition that might adversely affect its ability to perform its obligations hereunder.

7.2 Warranties by Agilent. Agilent warrants to Customer that (i) all Product supplied under this Agreement shall conform to the Specification at the time of delivery to Customer's carrier; (ii) all Product delivered under this Agreement shall be manufactured in accordance with cGMP; (iii) all Product delivered hereunder shall be free from Latent Defects; and (iv) all Product delivered

hereunder shall be delivered to Customer free and clear of all liens and security interests and other similar claims by Agilent. Agilent warrants to Customer that all Manufacturing Services shall be performed in a professional and workmanlike manner consistent with industry standards and applicable laws. The warranties set forth in this Section (i) survive acceptance of the Product or Manufacturing Services by Customer (including any Batch Packet acceptance); and (ii) are for the sole benefit of Customer.

7.3 IP Warranty by Agilent. Agilent warrants to Customer that, as of the Effective Date, to the best of Agilent's knowledge, the Process does not (i) infringe any Third Party patents issued as of the Effective Date or (ii) infringe or misappropriate any other intellectual property rights of any Third Party existing as of the Effective Date ("IP Warranty"). In the event of breach of the foregoing IP Warranty, Customer's sole and exclusive remedy, and Agilent's sole liability shall be as follows: (i) Agilent will defend or settle any Third Party claim against Customer, its officers, directors, employees, and contractors in accordance with Section 9.7, and (ii) in the event that a court of competent jurisdiction determines that the Process infringes the Third Party's intellectual property rights Agilent, at its cost and sole option, will either (a) with Customer's written consent, which consent shall not be unreasonably conditioned, withheld or delayed, modify the Process so that it is non-infringing or (b) obtain any necessary license.

7.4 Warranties by Customer. Customer warrants to Agilent that (i) as of the Effective Date, to the best of Customer's knowledge, it owns or has the necessary rights, title and interest in and to the Product, including the right under Patents owned or controlled by Customer to have Product made for Customer, and (ii) as of the Effective Date, Customer has not received any written notification alleging that the Product infringes or misappropriates the intellectual property rights of any Third Party.

7.5 Remedies. In the event that (a) the Product supplied under this Agreement fails to conform to the warranties set forth in Section 7.2 of this Agreement, (b) the Parties agree that the Product has a Latent Defect in accordance with Section 8.2.3.3 or an Independent Laboratory so determines in accordance with Section 8.2.3.5, or (c) the Product is not in Good Condition for any reason other than that the Product is not in the right quantity in accordance with the manifest, (i) Agilent may elect either to collect and dispose of the affected Product, at Agilent's expense, or to reimburse Customer for any reasonable costs incurred by Customer to collect and dispose of the affected Product; (ii) Agilent shall reimburse Customer for all reasonable costs incurred by Customer in connection with delivery of the affected Product, including freight, clearance, duty and storage charges; and (iii) Agilent shall promptly, at no additional cost to Customer (subject to Section
3.3.5 and 3.3.6, as applicable), (y) replace the affected Product as soon as reasonably practicable with Product that meets the requirements of Section 3.1 or (z) rework the affected Product within a reasonable timeframe, subject to mutual agreement of the Parties. In the event that Agilent fails to replace or rework the affected Product within the timeframe mutually agreed to by the Parties, Agilent will refund to Customer any amounts paid for such Product, and [**]. In the event that Manufacturing Services performed under this Agreement fail to conform to the warranty set forth in Section 7.2 of this Agreement, Agilent will promptly, at Agilent's cost, re-perform such Manufacturing Services, provided that Agilent receives notice from Customer within [**] after such Manufacturing Services were completely delivered. [**].

7.6 No Warranty to Third Parties. The warranties set forth in Section 7.2 and Section 7.3 are solely for the benefit of Customer. Agilent makes no warranty to Customer's end user customers or any other Third Party. Customer will not pass on to any end user customer or any other Third Party any warranty or representation on behalf of Agilent.

7.7 DISCLAIMER. THE WARRANTIES SET FORTH IN THIS ARTICLE 7 ARE EXCLUSIVE. THE REMEDIES SET FORTH IN SECTION 7.3 ARE EXCLUSIVE WITH RESPECT TO THE WARRANTIES IN SECTION 7.3. EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES NOR RECEIVES ANY WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF DESIGN, SUITABILITY OF QUALITY, OR ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE PRACTICE, WITH REGARD TO THE PRODUCT. AGILENT SPECIFICALLY

DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON- INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.

8. QUALITY

8.1 Quality Agreement. Each Party will comply with the terms of the Quality Agreement in the performance of its obligations hereunder including record retention, audits and inspections, change control, non-conformances, and product recall. The Parties will conduct periodic Product quality reviews in accordance with the terms of the Quality Agreement.

8.2 Quality Assurance.

8.2.1 Testing by Agilent. Agilent shall perform quality testing using assays mutually agreed to by the Parties in order to assure that Product complies with the Specification, and shall retain samples of Product as required by applicable law and produce records of the tests made on each Batch. Agilent shall provide Customer a Certificate of Analysis and Certificate of Compliance confirming the performance of such testing. Upon mutual agreement of the Parties and subject to the terms of the Quality Agreement, Customer may attend and observe any testing conducted by Agilent in accordance with this Section 8.2.1. In addition, no Product shall be delivered until such Product has been Processed in accordance with the agreed upon testing specifications; provided, however, that the foregoing shall not relieve Agilent of its obligation under this Section 8.2. With respect to PEG provided by Customer, Agilent shall perform quality testing of PEG in accordance with Agilent's approved standard operating procedures and report results to Customer within [**] of Agilent's receipt of PEG.

8.2.2 Records. Agilent shall maintain records, including Master Batch Records and Batch Production Records, with respect to the manufacturing and quality testing of the Product and shall deliver the Executed Batch Record (in electronic PDF format) to Customer prior to Agilent providing the complete Batch Documentation to Customer in accordance with the terms of the Quality Agreement. Agilent shall provide a point of contact, familiar with the Executed Batch Record, through which information about the Executed Batch Record can be obtained in a timely and organized manner to improve and expedite Customer review. In addition, Agilent will provide to Customer the Batch Documentation and Executed Batch Records in accordance with the terms of the Quality Agreement. Customer will review the Executed Batch Record to advise Agilent of any deficiencies or corrections needed with the Executed Batch Record in accordance with the terms of the Quality Agreement. Agilent will subsequently provide Customer a complete Batch Documentation (in electronic PDF format). Agilent shall not ship Product hereunder unless and until: (i) Agilent has provided to Customer the Batch Documentation for such Product and under the condition that all opened deviations, investigations or other anomalous events related to such Batch have been resolved, and (ii) Customer has reviewed the Batch Documentation for such shipment and authorized such shipment in writing. Upon receipt of a complete copy of the Batch Documentation, Customer will use commercially reasonable efforts to review such Batch Documentation, and advise Agilent of any deficiencies or corrections needed within [**] ("Target Review Period"). Upon Customer's request, during the Target Review Period [**] Agilent will make available for up to [**] the necessary personnel for in-person, on-site meetings at the Facility (or such other location as the Parties may agree, including virtually as appropriate) to facilitate Customer review of the Batch Documentation. If Customer is to exceed the Target Review Period, [**]. Following Agilent's resolution (to Customer's satisfaction) of any issues raised by Customer's review of the Batch Documentation, Agilent shall ship the Batch of Product. Notwithstanding the foregoing, in the event that (a) Customer fails to provide such authorization within [**] after Customer's receipt of the Batch Documentation, and (b) Customer has not within such [**] period submitted to Agilent any questions or requests for information and (c) Customer does not within such [**] period find fault or anomaly with the balance of the Batch Documentation, then Agilent may ship the associated Batch of Product and Customer shall be deemed to have accepted the Batch Documentation, [**].

8.2.3 Non-Conforming Product. Notwithstanding any prior acceptance of Product (including any Batch Documentation acceptance) by Customer, the following shall apply with respect to non-conforming Product:

8.2.3.1 Inspection/Testing. Upon receipt of each delivery of Product from Agilent under this Agreement, Customer shall report to Agilent within [**] of Customer's receipt of Product from Customer's carrier if the Product does not conform to the quantity specified in the Purchase Order, or if the Product is otherwise not in Good Condition.

8.2.3.2 Failure to Conform to Good Condition. In the event Customer notifies Agilent pursuant to Section 8.2.3.1 that the Product is not in Good Condition, Agilent shall have the right to inspect and analyze the Product within [**] of Agilent's receipt of the Product or Agilent's receipt of visual evidence demonstrating that the Product is not in Good Condition. In the event that the Parties agree that the Product was not in Good Condition at the time of delivery to Customer's carrier, Customer shall have the remedies as set forth in Section
8.2.3.6. If the Parties cannot agree as to whether the Product was in Good Condition at the time of delivery, the matter shall be escalated in accordance with Section 16.b, Escalated Dispute Resolution.

8.2.3.3 Latent Defect. In the event Customer discovers that the Product has a Latent Defect, Customer shall promptly notify Agilent in writing providing specific details about the nature of the Latent Defect.

8.2.3.4 Notification from Customer. In the event Customer notifies Agilent pursuant to Section 8.2.3.3 that the Product has a Latent Defect, (i) Agilent shall have the right to inspect and analyze the Product within [**] of Agilent's receipt of a suitable quantity of such Product and (ii) the Parties shall work together in good faith to reach agreement as to whether the Product has a Latent Defect. In the event the Parties agree that the Product has a Latent Defect, Customer shall have the remedies set forth in Section 7.5.

8.2.3.5 Independent Laboratory. In the event the Parties fail to agree whether the Product has a Latent Defect, the matter shall be referred to an Independent Laboratory. Agilent shall forward a sample of retained Product from the Batch in question to the Independent Laboratory for testing and control purposes. Customer may also forward a sample of the affected Product to the Independent Laboratory for such evaluation. The Parties shall mutually agree to the controls and procedures used by the Independent Laboratory to test the Product. Each Party shall have the right to audit the Independent Laboratory to determine whether there was any departure from the established controls and procedures used to test the Product. In the event a Party determines that there was a departure from the established controls and procedures, the Party shall notify the other Party in writing within [**] and the Parties shall resolve the matter in accordance with Section 16.b. In the absence of such determination, the decision of the Independent Laboratory shall be final and binding on the Parties. If the Independent Laboratory determines that the Product has a Latent Defect, then the Independent Laboratory's fees shall be borne by Agilent and Agilent shall [**] in connection with the Independent Laboratory's analysis of the Product. If the Independent Laboratory determines that the Product does not have a Latent Defect, then Customer shall bear the Independent Laboratory's fees and reimburse Agilent for any reasonable direct costs incurred by Agilent in connection with the Independent Laboratory's analysis of the Product.

8.2.3.6 Customer's Remedies. In the event that the Product is not in Good Condition, or in the event that the Product has a Latent Defect, the remedies set forth in Section 7.5 shall apply.

8.2.4 Audit Rights. Customer shall have the right to conduct audits and inspections of the Facility, Agilent's manufacturing operations and Agilent's records relating to this Agreement as provided in the Quality Agreement. Agilent shall cooperate with Customer

in conducting such audits and inspections, including scheduling any requested audit to take place in accordance with the Quality Agreement.

8.2.5 Observation by Customer. During the Term, Customer shall have the right to visit the Facility (such as through person-in-plant visits) in order to ensure that the Processing complies with applicable legal requirements and the Specification, as applicable, in accordance with any Agilent policies and procedures for the Facility and the Quality Agreement. Such visits shall not interfere with Agilent's operations.

8.2.6 Recalls and Voluntary Withdrawals. If either Party becomes aware of information about the Product or Finished Product indicating that it may be non-conforming Product or Finished Product or that there is potential adulteration, misbranding and/or any potential issues regarding the safety or effectiveness of the Product or Finished Product, it shall provide notice, investigate and attempt to resolve such issue in accordance with the Quality Agreement. Customer shall bear all costs associated with a recall of the Finished Product except to the extent such recall is caused by a Latent Defect, in which case Agilent shall pay [**]. The determination as to each Party's [**]. For purposes of this Section, the costs associated with a recall of the Finished Product are defined as [**]. In the event of a dispute with respect to responsibility for costs associated with a recall, such dispute shall be escalated for resolution in accordance with Section 16(b).

9. INTELLECTUAL PROPERTY

9.1 Background Property. The Intellectual Property of each of Agilent and Customer existing prior to the Effective Date of this Agreement shall remain the separate and exclusive property of each Party and except as otherwise expressly set forth in this Article 9, are not affected by this Agreement. Subject to the rights expressly granted by one Party to the other Party in this Agreement, neither Party shall have any right or claim in the Intellectual Property belonging to the other Party. For clarity, the Intellectual Property rights of the Parties agreed in Statements of Work governing Manufacturing Services that were entered into before the Effective Date are not affected by this Agreement.

9.2 Ownership of Developed Intellectual Property.

9.2.1 The sequence information for the Product provided by Customer to Agilent pursuant to this Agreement shall remain the property of Customer. Agilent, its affiliates, employees, agents, consultants, and subcontractors shall not disclose or use such sequence information except in accordance with the terms of this Agreement, unless they receive prior express written consent of Customer. Customer understands and agrees that this duty of non-disclosure does not extend to similar or identical sequences provided to Agilent by Third Parties that, to Agilent's knowledge, are not under a duty of confidentiality to Customer. All Intellectual Property developed, invented, discovered, or conceived in connection with work conducted under this Agreement specifically relating to the Product, including its structure, sequence and/or end-caps, purity profile and specifications, excluding, however, any Agilent IP ("New Customer IP") shall belong exclusively to Customer. Agilent hereby assigns to Customer all of its right, title and interest in the New Customer IP.

9.2.2 All Intellectual Property developed, invented, discovered, or conceived by Agilent and/or Customer in connection with work conducted under this Agreement relating to (i) Agilent's processes for oligonucleotide manufacturing, (ii) [**], (iii) Agilent's methodology of analyzing oligonucleotides, including analytical methods developed by Agilent under this Agreement and (iv) the Process, in each case, shall belong to Agilent (collectively, the "Agilent IP"). Customer hereby assigns to Agilent all of its right, title, and interest in the Agilent IP. "Process" means the combination of materials, procedures, test methods, and controls used by Agilent to manufacture the Product under this Agreement, which may include without limitation the following unit operations: [**]. The Parties acknowledge and agree that the [**]. For the purposes of clarity: (a) [**]; and (b) [**], the Parties acknowledge and agree that [**]. Agilent shall [**] and if Agilent [**], then such [**], the Parties shall [**].

9.2.3 Each Party agrees to execute such assignments and other documents and to take such other actions as may be reasonably requested by the other Party from time to time, at the

other Party's expense, in order to effect the ownership and assignment provisions of Sections 9.2.1 and 9.2.2.

9.3 License Grants.

9.3.1 License to Agilent.

9.3.1.1 Customer hereby grants to Agilent a limited, non-exclusive, royalty-free, non-transferable, and non-assignable (except in accordance with Section 16.e.) license during the term of this Agreement, without the right to sublicense except as pre-approved in writing by Customer, to use the Customer IP solely as necessary to perform services in accordance with the terms and conditions of this Agreement. "Customer IP" means (i) all intellectual property owned, licensed, or developed by or on behalf of Customer relating to the sequence and the molecular, chemical and/or compositional structure of the Product, including all New Customer IP and (ii) all other Intellectual Property owned, licensed, or developed by or on behalf of Customer before the Effective Date or owned, licensed, or developed by or on behalf of Customer independent of this Agreement and without reliance on the Confidential Information of Agilent.

9.3.2 Licenses to Customer.

9.3.2.1 Agilent hereby grants to Customer [**].

9.3.2.2 In addition to the non-exclusive license granted above and [**], Agilent hereby grants to Customer [**].

9.3.2.3 Agilent confirms to Customer that as of the Effective Date, [**] by Agilent or its Affiliates. If Agilent or its Affiliates during the Term or thereafter [**], Agilent will [**] in this Section 9.3.2.

9.3.3 Third Party Licenses. Customer's use of the Product and Finished Product and request that Agilent supply the services with respect to the Product may necessitate Customer's procurement of separate licenses from Third Parties for Intellectual Property that claims or covers the Product or Finished Product. Subject to Agilent's obligations under Section 9.6, Customer shall have full responsibility for the determination of whether and from which Third Party it requires any such license(s) to Intellectual Property and for the procurement of such license(s).

9.4 Reservation of Rights. Except as expressly provided herein, no license to any Agilent Intellectual Property or Customer Intellectual Property is granted, conveyed or implied. All rights not conferred are expressly reserved.

9.5 Subcontracting. Agilent shall only engage those Affiliates and Third Parties approved by Customer in writing to manufacture the Product and shall not sub-license the rights under any Customer Intellectual Property other than to such approved Affiliates and Third Parties and solely for the purpose of manufacturing and supplying Product to Customer and provided that any such approved Affiliate or Third Party shall be subject to Agilent's obligations contained in this Agreement. Agilent shall be responsible for any breach of this Agreement by any such Affiliates and Third Parties subject to Article 15.

9.6 Licenses to Use the Process. Agilent is responsible for the procurement of any licenses to Intellectual Property necessary to use the Process to manufacture the Product under this Agreement. Agilent shall have full responsibility for the determination of whether and from which Third Party it requires any such license to Intellectual Property claiming or covering the Process for the manufacture of the Product under this Agreement and for the procurement of any such license. For purposes of clarity, nothing in this Section 9.6 shall limit or prevent Customer, in its sole discretion, from obtaining any license or other rights to any Third Party Intellectual Property it considers necessary or useful to manufacture the Product.

9.7 Third Party IP Existing as of the Effective Date. Agilent will defend or settle any Third Party claim against Customer, its officers, directors, employees, and contractors that (i) Agilent's use of the Process to manufacture the Product under this Agreement or (ii) any Manufacturing Services provided by Agilent under this Agreement (a) infringes any Third Party patents issued as of the Effective Date or (b) infringes or misappropriates any other intellectual property rights of any Third Party existing as of the Effective Date. Agilent shall not settle or compromise any action or

proceeding under this Section 9.7 that adversely affects Customer's rights and interests without the written consent of Customer, which consent shall not be unreasonably conditioned, withheld or delayed. The Parties shall comply with the indemnification process set forth in Section 10.3 with respect to any such Third Party claims. Agilent will pay infringement defense costs, settlement amounts and court awarded damages in connection with infringement claims under this Section 9.7. Agilent shall have no obligation under this Section 9.7 for any claim of infringement to the extent arising from Product use prohibited by this Agreement. This Section 9.7 states Customer's sole and exclusive remedy and Agilent's sole liability with respect to any such Third Party claim.

9.8 Third Party IP Arising after the Effective Date. In the event of a claim or allegation that the Process or the Manufacturing Services (a) infringes any Third Party patents issued after the Effective Date or (b) infringes or misappropriates any other intellectual property rights of any Third Party that first came into existence after the Effective Date, the Party first having notice of the claim or assertion shall promptly notify the other Party and the Parties shall negotiate in good faith and jointly determine (i) any necessary or desirable action to remediate the same, which may include modifying the Process so that it is non-infringing, obtaining any necessary license and/or opposing the claim or allegation, and (ii) an equitable allocation of related costs.

10. INDEMNITIES AND INSURANCE

10.1 Agilent's Indemnity Obligations. Agilent will indemnify, defend and hold harmless Customer, its officers, directors, and employees, from and against any and all claims, losses, damages, demands, expenses or other liability arising out of a Third Party claim to the extent caused by (i) failure of the Product to conform to the Specification at the time of delivery to Customer's carrier; (ii) Agilent's failure to manufacture the Product in accordance with cGMP; or (iii) the negligence or willful misconduct of Agilent or its officers, directors, employees, Affiliates, subcontractors or suppliers. Agilent's obligations under this Section 10.1 do not apply with respect to any claim to the extent such claim is subject to indemnification under Section 10.2.

10.2 Customer's Indemnity Obligations. Customer will indemnify, defend and hold harmless Agilent, its officers, directors, and employees, from and against any and all claims, losses, damages, demands, expenses or other liability arising out of a Third Party claim to the extent (i) arising from the sale, marketing or distribution of the Product or Finished Product, or use of the Product or Finished Product, by Customer or its officers, directors or employees or any Third Party including death or injury to any person; or (ii) caused by the negligence or willful misconduct of Customer or its officers, directors or employees, Affiliates, subcontractors or suppliers. Customer's obligations under this Section 10.2 do not apply with respect to any claim to the extent such claim is subject to indemnification under Section 10.1.

10.3 Process. Each Party agrees to notify the other Party promptly upon receipt of any claim for which indemnification is sought. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. In no event may either Party compromise or settle any claim or suit in a manner that adversely affects the rights and interests of the other Party (or any indemnitee) without the prior written consent of the other Party, which consent shall not be unreasonably conditioned, withheld or delayed. The indemnifying Party shall have no liability under this Article 10 with respect to claims or suits settled or compromised by the indemnified Party (or any indemnitee) without the indemnifying Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. The indemnified Party may, at its own expense, participate in the defense of any claim. In the event that the indemnifying Party fails to assume control of the defense of any claim, the indemnified Party may assume control at the expense of the indemnifying Party.

10.4 Insurance. During the Term and for [**] thereafter, Agilent will maintain insurance coverage in accordance with the Memorandum of Insurance attached hereto as Exhibit C.

11. COMPLIANCE WITH LAWS AND REGULATORY MATTERS

11.1 Compliance with Laws. Each Party shall comply with all applicable laws and regulations governing the performance of such Party's obligations under this Agreement. Without limiting the foregoing, Agilent shall ensure that the Facility and Product conform to cGMP and the

requirements of all applicable Regulatory Authorities and Customer shall ensure that the Finished Product conforms to cGMP and the requirements of all applicable Regulatory Authorities.

11.2 Regulatory Filings. Customer, at its expense, shall be solely responsible for the preparation, filing and maintenance of all regulatory documents and all governmental permits, licenses and other approvals as may be necessary with respect to the formulation, marketing, distribution, sale and use of the Product and Finished Product. Upon Agilent's request, Customer will provide Agilent with a copy of such regulatory documents to the extent they relate to the manufacture of Product under this Agreement.

11.3 Codes of Conduct. Agilent agrees to maintain, in accordance with industry practices, and comply with Agilent's Standards of Business Conduct available at http://www.agilent.com/supplier/downloads/StandardsBusinessConduct.pdf.

11.4 Permits. Agilent at its expense shall be solely responsible for, and has the obligation to prepare, file and maintain all licenses, permits and approvals as may be necessary with respect to the manufacture of the Product and performance of Manufacturing Services at the Facility, including all regulatory approvals required to import raw materials and packaging components. Upon Customer's request, Agilent will provide Customer with a copy of such documents to the extent they relate to the manufacture of the Product or the performance of Manufacturing Services under this Agreement.

11.5 Hazardous Waste. Any hazardous waste generated during the manufacture of the Product under this Agreement will be disposed of by Agilent in accordance with Agilent procedures and applicable laws and regulations at Agilent's cost and expense. Agilent and Customer will endeavor to identify opportunities to minimize and potentially reuse waste and other byproducts from the Process.

11.6 Export Controls. Each Party shall comply with applicable US and other laws, rules and regulations that govern the import, export and re-export of the Product, including the U.S. Export Administration Regulations, and will obtain any required export and import authorizations.

11.7 Record Retention. Agilent shall maintain the records and documentation relating to the manufacture of the Product in accordance with FDA and ICH guidances, Agilent's Standard Operating Procedure and the Quality Agreement.

11.8 Technical Support.

11.8.1 Upon notification to Agilent that Customer has received a complaint or inquiry regarding the safety, efficacy or quality of the Product or Finished Product, Agilent shall, within a reasonable period, supply Customer with a chemical analysis of a number of retained samples, maintained in accordance with the Quality Agreement, of the Batch(es) of the Product in question.

11.8.2 Upon notification to Customer that Agilent has received a complaint or inquiry regarding any issues relating to the safety, efficacy or quality of the Product or Finished Product, Customer shall, within a reasonable period, provide technical support as reasonably requested by Agilent, which may include, but shall not be limited to, technical advice and chemical analysis of retained samples of the Product, maintained in accordance with the Quality Agreement.

11.8.3 Except as set forth in Section 8.2.6, all technical support provided by Agilent under this Section 11.8 shall be subject to the pricing and payment terms for technical and regulatory support as set forth in a Statement of Work agreed upon by the Parties.

11.9 Regulatory Support.

11.9.1 Agilent agrees to cooperate with, and provide regulatory assistance to, Customer to support existing, pending or new Product or Finished Product registrations and marketing approvals, in each case, with any relevant governmental authority. The foregoing assistance rendered by Agilent may include: (i) assisting Customer in completing and submitting changes to any regulatory submissions related to the Product;
(ii) cooperation in connection with pre-approval inspections carried out by governmental authorities; and (iii) providing information to Customer that may be required by a relevant governmental authority to support the Product or Finished Product, including the manufacturing and exportation related thereto. Except as set forth in Section 8.2.6

and except for the general requirements for API manufacturers set forth in the cGMP and all laws and regulations applicable to the manufacture and supply of API, all Product-specific regulatory support provided by Agilent under this Section 11.9 shall be subject to the pricing and payment terms for technical and regulatory support as set forth in a Statement of Work agreed upon by the Parties.

11.10 FDA Debarment Statement. Agilent hereby certifies that neither Agilent nor any employee or subcontractor engaged by Agilent to perform services under this Agreement has been debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with the performance of services under this Agreement or any comparable law or regulation outside of the United States. In the event that Agilent becomes aware of any such debarment, Agilent will provide Customer with written notice thereof immediately. Agilent will request that all cGMP manufacturing and testing subcontractors utilized pursuant to Section 5.12 of the Quality Agreement provide Customer with a certification that is substantially similar to the certification provided by Agilent in this Section 11.10. In the event that any such subcontractor fails to provide the certification, Customer may withdraw its approval for such subcontractor and Agilent shall cease using such subcontractor to provide services under this Agreement.

11.11 Environmental, Social and Governance (ESG) Reporting. If requested by Customer, Agilent will use commercially reasonable efforts to cooperate and provide such data and information for purposes of Customer complying with any ESG reporting requirements (whether voluntary or mandatory), subject to the provisions of Article 14. To the extent such information is not readily available or prepared by Agilent for Third Party customers, Agilent may charge Customer for such information at reasonable rates.

12. FORCE MAJEURE

Neither Party will be liable for any failure or delay in performance of its obligations under this Agreement to the extent such failure or delay is caused by any event beyond such Party's reasonable control, including fire, flood, explosion, unavailability of utilities or raw materials, labor difficulties, war, riot, act of God, export control regulation, or other laws or regulations, action or failure to act of any governmental authority, or any judgment, injunction or order of a court, administrative agency or regulatory authority having the effect of preventing or materially adversely affecting either Party's performance under this Agreement. If such event occurs, the affected party shall use commercially reasonable efforts to mitigate or limit the effects of such event and shall resume performance with reasonable dispatch upon cessation of such event.

13. TERM AND TERMINATION

13.1 Term. Unless otherwise terminated under this Article 13, this Agreement will commence as of the Effective Date and will continue for seven (7) years from the date of Regulatory Approval in the United States of a New Drug Application for the Finished Product (the "Initial Term"). Unless otherwise terminated in accordance with this Article 13, this Agreement shall be automatically extended for successive two (2) year periods (each, a "Renewal Term" and all such Renewal Terms together with the Initial Term, the "Term") unless either Party provides to the other Party written notice of intent not to renew at least [**] prior to the end of the then-current Term.

13.2 Termination.

(a) Subject to Section 13.2(c), this Agreement or a Statement of Work may be terminated by either Party upon [**] written notice in the event of a material breach of Customer's payment obligations under Section 6.2 or [**] written notice in the event of a material breach of any other provision of this Agreement or such Statement of Work; provided, however, that the breaching Party will have an opportunity to (i) cure the breach during the [**] or [**] (as applicable), or (ii) provide the non-breaching Party with a plan to remedy the breach within the [**] or [**] (as applicable), and if so cured, no termination will be deemed to have occurred as long as the breaching Party diligently pursues the plan to remedy the breach and completes such plan in accordance with the time frame mutually agreed to by the Parties (such time frame not to exceed an additional [**]).

(b) This Agreement may be terminated by either Party immediately upon written notice to the other Party (i) if the other Party makes an assignment for the benefit of creditors; (ii) if proceedings in voluntary or involuntary bankruptcy are initiated by, on behalf of or against the

other Party (and, in the case of any such involuntary proceeding, not dismissed within [**]); (iii) if the other Party is adjudicated bankrupt, files a petition under insolvency laws, is dissolved or has a receiver appointed for substantially all of its property; or (iv) if the other Party ceases operation of its business as its business has normally been conducted.

(c) In the event of either Party's material breach of its confidentiality obligations under Article 14, the Parties shall refer the matter for resolution under the escalated dispute resolution process set forth in Section 16.b. For the avoidance of doubt, [**].

(d) Customer may terminate this Agreement immediately if any Regulatory Authority issues a final order or determination that prevents Customer from supplying the Product or Finished Product or exporting, purchasing or selling the Product or Finished Product. Additionally, Customer shall have the right to terminate this Agreement immediately if the Product or Finished Product cannot be reasonably commercialized for medical, scientific or legal reasons, including reasons arising out of clinical trials.

(e) In the event that Agilent has failed to cure any Supply Failure under this Agreement, in accordance with the provisions set forth in Section 4.11.1, within [**] of such Supply Failure, Customer may terminate this Agreement upon written notice to Agilent.

13.1 Effect of Termination or Expiration.

13.3.1 In the event of termination of this Agreement for any reason other than (i) termination by Agilent pursuant to Section 13.2(a) or (ii) termination by Agilent pursuant to Section 13.2(b), Customer shall be entitled, subject to the terms of this Agreement, to [**] in effect at the date of such termination.

13.3.2 In the event of termination of this Agreement for any reason other than (i) termination by Customer pursuant to Section 13.2(a), (ii) termination by Customer pursuant to Section 13.2(b), or (iii) termination by Customer pursuant to Section 13.2(e), Customer shall promptly pay Agilent a cancellation fee pursuant to Section 4.7 for all Batches included in the Binding Forecast in effect at the date of such termination (though, if mutually agreed, Customer may place Purchase Orders for such Batches pursuant to Section 4 in lieu of paying the cancellation fee pursuant to this Section).

13.3.3 Termination or expiration of this Agreement or any Statement of Work shall not release either Party from any liability, right of action or other obligation which has arisen prior to such termination or expiration, including Agilent's obligation to deliver to Customer such quantity of Product under any Purchase Order accepted by Agilent prior to the effective date of termination or expiration, and Customer's obligation to pay Agilent the amount set forth in such Purchase Order. In the event of termination of any Statement of Work under Section 13.2, Customer shall only pay Agilent for all work performed under such Statement of Work prior to the termination date.

13.2 Surviving Provisions. Notwithstanding any expiration or termination of this Agreement, the following provisions shall survive: 3.3.5, 3.3.6, 3.5.1, 4.7, 4.11.4, 6.2, 6.3, 7, 8.2.3, 8.2.6, 9, 10, 11, 12, 13.3 and 13.4, 14, 15 and 16, and related definitions.

14. CONFIDENTIAL INFORMATION

14.1 Proprietary Information. The terms and conditions of the Confidentiality Agreement dated March 22, 2011, by and between Customer and Agilent, as amended ("Confidentiality Agreement"), are attached hereto as Exhibit D and incorporated herein by this reference. Capitalized terms used in this Article 14 and not defined in this Agreement shall have the meanings ascribed to them in the Confidentiality Agreement. The terms and conditions of the Confidentiality Agreement shall apply to information exchanged under this Agreement; provided that:

14.1.1 with respect to information exchanged pursuant to this Agreement, the "Purposes" as defined in Section 1 of the Confidentiality Agreement shall be amended to mean the conduct of activities and exercise of rights granted pursuant to this Agreement;

14.1.2 notwithstanding Section 8(c) of the Confidentiality Agreement, the Confidentiality Agreement, as it applies to information exchanged under this Agreement, shall be

construed and interpreted in accordance with the laws of the State of New York as provided in Section 16(k);

14.1.3 notwithstanding Section 8(e) of the Confidentiality Agreement, the obligations of confidentiality and non-use under the Confidentiality Agreement shall apply until the [**] anniversary of the expiration or termination of this Agreement;

14.1.4 the restrictions on disclosure and use set forth in the Confidentiality Agreement shall not apply to the disclosure of this Agreement or the disclosure of Proprietary Information to governmental authorities (i) that is required by applicable law or regulation to be submitted by Customer in connection with the application for, issuance or maintenance of Regulatory Approvals for the Product or Finished Product; (ii) that is submitted by either Party to comply with requests for information from any governmental authority; or (iii) that is submitted by either Party to comply with applicable governmental regulations (including the rules and regulations of any stock exchange); provided that, (x) to the extent permitted by applicable law, Customer or Agilent, as the case may be, will (1) give reasonable advance notice to the other Party of such disclosure requirement in order to allow the other Party the opportunity to seek appropriate legal relief to prevent or limit disclosure of its Proprietary Information, and (2) if submission of this Agreement in redacted form is permitted by applicable governmental regulations, provide to the other Party for its review such redacted Agreement and obtain the other Party's prior written consent of such redactions for submission, which consent shall not be unreasonable withheld, delayed, or conditioned; (y) reasonable measures shall have been taken by the Party seeking to disclose the other Party's Proprietary Information to ensure confidential treatment of such Proprietary Information; and (z) any disclosure shall be limited to such portion of the other Party's Proprietary Information that is legally required to be disclosed.

14.1.5 notwithstanding anything to the contrary in the Confidentiality Agreement, but subject to Section 14.1.1, in the event that the Recipient wishes to disclose this Agreement or the Disclosing Party's Proprietary Information to actual or potential investors, lenders, acquirers, merger partners, or professional advisors who have a reasonable need to know such information, the Recipient shall provide prior written notice thereof to the Disclosing Party, and the Parties shall promptly meet (in person or via telephone) and confer prior to any such disclosure for the purpose of avoiding any inappropriate disclosure of the Disclosing Party's Proprietary Information. Following such meeting, if the Disclosing Party has provided its express prior written consent to such disclosure, which consent shall not be unreasonably withheld or delayed, the Recipient may disclose the Disclosing Party's Proprietary Information to such Third Party; provided that (i) the Recipient shall only disclose such amount of the Disclosing Party's Proprietary Information as is reasonably necessary; and (ii) the Recipient has entered into a confidentiality agreement, with terms of confidentiality at least as restrictive as the terms and conditions set forth in this Article 14 and the Confidentiality Agreement, with such Third Party (other than attorneys and accountants of Recipient who are bound to confidentiality under applicable ethical and professional rules) before disclosing any of the Disclosing Party's Proprietary Information. In the event that the Disclosing Party has not consented to such disclosure, the Recipient may engage an independent Third Party consultant reasonably acceptable to the Disclosing Party and subject to confidentiality obligations at least as restrictive as the terms and conditions set forth in this Article 14 and the Confidentiality Agreement, to evaluate the Parties' rights and obligations hereunder and such independent Third Party consultant shall be permitted to disclose to such Third Party confirmation solely regarding the adequacy of such rights and obligations and the performance hereunder. For the avoidance of doubt, the independent Third Party consultant shall not be permitted to disclose any Proprietary Information of the Disclosing Party to any Third Party. The Parties agree that the process set forth in this Section 14.1.5 shall not apply to Customer's use or exercise of the license rights under Section 9.3.2, provided that Customer complies with the provisions of Section 9.3.2.

14.2 Remedies. Each Party shall be entitled, in addition to any other right or remedy it may have, at law, in equity or under this Agreement, to seek temporary, preliminary and permanent

injunctions, enjoining or restraining the other Party and its Affiliates from any violation or threatened violation of this Article 14.

15. **LIMITATION OF LIABILITY**

15.1 EXCEPT IN CONNECTION WITH (A) A BREACH OF ARTICLE 14; (B) THIRD PARTY CLAIMS UNDER ARTICLE 10; AND (C) DAMAGES ARISING FROM GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT WILL EITHER PARTY OR ITS AFFILIATES, SUBCONTRACTORS OR SUPPLIERS BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS, LOST OPPORTUNITY OR LOST GOODWILL, ARISING OUT OF THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THIS EXCLUSION IS INDEPENDENT OF ANY OTHER REMEDY SET FORTH IN THIS AGREEMENT. NOTWITHSTANDING THE FOREGOING, AGILENT SHALL PAY ALL SETTLEMENT AMOUNTS AND COURT AWARDED DAMAGES IN ACCORDANCE WITH SECTION 9.7 OR 9.8, PROVIDED THAT THE PARTIES HAVE COMPLIED WITH THE INDEMNIFICATION PROCESS SET FORTH IN SECTION 10.3.

15.2 EXCEPT IN CONNECTION WITH (A) A BREACH OF ARTICLE 14; (B) THIRD PARTY CLAIMS UNDER SECTION 9.7, 9.8 OR ARTICLE 10; (C) DAMAGES CAUSED BY AGILENT'S OR ITS OFFICERS', DIRECTORS', EMPLOYEES', AFFILIATES', SUBCONTRACTORS' OR SUPPLIERS' GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (D) AGILENT'S OBLIGATIONS TO CREDIT CUSTOMER UNDER SECTIONS 3.3.5 AND 3.3.6; (E) THE REMEDIES SET FORTH IN SECTION 7.5; (F) RECALL COSTS UNDER SECTION 8.2.6; AND (G) OBLIGATIONS OF AGILENT TO REFUND OR CREDIT AMOUNTS TO CUSTOMER UNDER SECTIONS 4.7, 4.11.1, 7.5 AND 13.3.3, TO THE FULLEST EXTENT PERMITTED BY LAW, AGILENT'S AGGREGATE LIABILITY TO CUSTOMER DURING ANY GIVEN [**] PERIOD FOR CLAIMS FOR DAMAGES UNDER THIS AGREEMENT SHALL NOT EXCEED THE SUM OF (I) [**] PLUS (II) [**].

16. **MISCELLANEOUS**

a. Notices. All notices required or permitted to be given under this Agreement must be in writing and delivered to the other Party as set forth below. Notices are validly given upon the earlier of confirmed receipt by the receiving Party; or if sent by courier, three (3) days after dispatch by a reputable courier or certified mail, return receipt requested; or if sent by email, the next business day after the sending of such email. Either Party may change its designated contact and address for purposes of notice by giving notice to the other Party in accordance with these provisions.

Agilent Technologies, Inc. IVERIC bio, Inc.
5555 Airport Blvd. notices@ivericbio.com
Suite 100
Boulder, CO 80301
Attn: General Manager Attn: Legal Department

With a copy to:

Agilent Technologies, Inc. IVERIC bio, Inc.
5301 Stevens Creek Blvd. 8 Sylvan Way
Santa Clara, CA 95051 Parsippany, NJ 07054
Attn: General Counsel Attn: Chief Operating Officer

b. Escalated Dispute Resolution. In the event that the Parties are unable to agree upon any disputes arising under this Agreement, including without limitation any claims of breach that may give rise to termination, the Parties' relationship managers agree to negotiate in good faith to resolve any such disputes. If such negotiations and meetings do not resolve the dispute within [**] after notice

of the dispute, then a senior executive from each Party will meet face to face within [**] or as mutually agreed between them to attempt to resolve such dispute. If the dispute is not resolved to the satisfaction of these executives within [**], then either Party may, subject to the provisions of this Agreement, pursue all available legal remedies. Notwithstanding the foregoing, either Party may seek temporary or injunctive relief with respect to any disputed matter without following the dispute resolution procedures set forth above.

c. Exhibits. The following Exhibits attached to this Agreement are deemed a part of this Agreement and incorporated by reference herein:

EXHIBIT A PRODUCT

EXHIBIT B FORECAST

EXHIBIT C MEMORANDUM OF INSURANCE

EXHIBIT D CONFIDENTIALITY AGREEMENT

EXHIBIT E PRODUCT PRICING

EXHIBIT F SPECIFICATION

d. Independent Contractors. The relationship of the Parties established under this Agreement is that of independent contractors and neither Party is a partner, employee, agent or joint venturer of or with the other.

e. Assignment. Except as otherwise provided in this Section 16(f), neither this Agreement nor any part hereof may be assigned or transferred by either Party, whether by operation of law or otherwise, without the other Party's prior written consent. Either Party shall have the right to assign this Agreement, without the other Party's consent, to any Affiliate or in the event of a sale or transfer of the business as to which this Agreement relates, whether such sale or transfer occurs by merger, reorganization, asset and/or stock purchase, or by any other means, provided that the assignee agrees in writing to assume all of the assignor's obligations under this Agreement. The assigning Party shall notify the non-assigning Party in writing as soon as possible of any sale or transfer of its business. Any assignment or purported assignment in violation hereof shall be void. This Agreement will be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

f. Headings; Construction; Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause or Exhibit, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (i) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (ii) any reference to any law refers to such law as from time to time enacted, repealed or amended; (iii) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision

hereof; (iv) the words “include,” “includes,” “including,” “exclude,” “excludes,” and “excluding,” shall be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import; and (v) all references in this Agreement to “days” will, unless otherwise specified herein, mean calendar days.

g. No Third Party Beneficiaries. No provisions of this Agreement are intended to confer or give, or will be construed to confer or give, to any person or entity other than Agilent and Customer any rights, remedies or other benefits under or by reason of this Agreement.

h. Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid or unenforceable in any respect, such determination will not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct. To the extent that any such provision is found to be invalid, illegal or unenforceable, the Parties will negotiate in good faith to substitute for such provision, to the extent possible, a new provision that most nearly effects the Parties’ original intent in entering into this Agreement or to provide an equitable adjustment in the event no such provision can be added. The other provisions of this Agreement will remain in full force and effect.

i. Hierarchy Of Documents. Unless otherwise specifically agreed to by the Parties, in the event of any conflict between the terms of this Agreement and its Exhibits, and a Purchase Order, the order of precedence is as follows: (i) the terms of this Agreement; (ii) its Exhibits; and (iii) the terms of the accepted Purchase Order. The Parties acknowledge and agree that the pre-printed provisions on any Purchase Order will be deemed deleted and of no effect whatsoever.

j. Entire Agreement. This Agreement together with the Quality Agreement and any Purchase Orders and Statements of Work constitutes the entire agreement between the Parties with respect to the subject matter hereof and subject to the following sentence, supersedes all prior communications, representations or agreements, whether oral or written, relating to the subject matter of this Agreement. For purposes of clarity, Agilent and Customer have entered into statements of work and purchase orders for manufacture and supply of the Product for commercial purposes before the Effective Date; the Parties agree that the manufacture and supply of commercial Product under those statements of work and purchase orders shall be governed by this Agreement. A breach of the Quality Agreement shall be deemed a breach of this Agreement. No modifications, amendments, or waiver of any term, condition or provision of this Agreement or any Purchase Order or Statement of Work will be binding on either Party unless in writing and signed by an authorized representative of each Party.

k. Governing Law. This Agreement is made under and will be construed in accordance with the laws of New York without giving effect to that jurisdiction's choice of law rules. The United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement or to transactions processed under this Agreement.

l. Announcements. Neither Party shall make any public disclosure relating to this Agreement without the prior consent of the other Party, except as otherwise permitted under Article 14.

m. Subcontractors. Agilent shall not, without the prior written approval of Customer, subcontract or delegate its obligations under this Agreement or a Statement of Work. Agilent shall be responsible for ensuring that any approved subcontractor, including Agilent’s Affiliates, shall be subject to Agilent’s obligations contained in this Agreement or any applicable Statement of Work. Agilent shall be responsible for any breach of this Agreement by any subcontractors subject to Article 15.

n. Counterparts. This Agreement or any Purchase Order or a Statement of Work may be executed in counterparts each of which, when executed and delivered, shall be original, but all such counterparts shall constitute one and the same document. The Parties agree that signatures transmitted via portable document format (PDF) shall be deemed originals until originals replace such copies.

APPROVED AND AGREED TO:

AGILENT TECHNOLOGIES, INC. IVERIC BIO, INC.

By:/s/ Brian Carothers By: /s/ Glenn Sblendorio

Typed Name: Brian Carothers Typed Name: Glenn Sblendorio

Title: VP NASD Title: CEO

Date: 3/17/2023 Date: 3/17/2023

EXHIBIT A

PRODUCT

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

EXHIBIT E

PRODUCT PRICING

Pricing for the [**] Process will be as follows: **$ [**] per Batch**

Pricing for the [**] Process will be **on a per gram basis to be agreed upon by the Parties following scale-up of such Process in an amendment to this Agreement.**

Exhibit 31.1

CERTIFICATIONS

I, Glenn P. Sblendorio, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of IVERIC 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: May 10, 2023

By: /s/ Glenn P. Sblendorio

Glenn P. Sblendorio
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, David F. Carroll, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of IVERIC 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: May 10, 2023

By: /s/ David F. Carroll

David F. Carroll
Chief Financial Officer
(Principal Financial 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 on Form 10-Q of IVERIC bio, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Glenn P. Sblendorio, Chief Executive Officer of the Company, hereby certifies, pursuant to Rule 13a-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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: May 10, 2023

By: /s/ Glenn P. Sblendorio

Glenn P. Sblendorio
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 on Form 10-Q of IVERIC bio, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David F. Carroll, Chief Financial Officer of the Company, hereby certifies, pursuant to Rule 13a-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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: May 10, 2023

By: /s/ David F. Carroll
David F. Carroll
Chief Financial Officer
(Principal Financial Officer)