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 September 30, 2022

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 October 31, 2022 there were 120,722,802 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:

- 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 (Zimura®) for the treatment of Geographic Atrophy (GA) secondary to AMD, and from GATHER2, our ongoing Phase 3 clinical trial evaluating avacincaptad pegol for the treatment of GA secondary to AMD, on our business and regulatory strategy, including our plans to submit a new drug application to the U.S. Food and Drug Administration (FDA) and a marketing authorization application to the European Medicines Agency (EMA);
- the timing, costs, conduct and outcome of GATHER2, including expectations regarding patient retention and the safety profile of avacincaptad pegol, including from our open-label extension study for patients who completed the GATHER2 trial, and expectations regarding the potential for avacincaptad pegol to receive regulatory approval for the treatment of GA based on the clinical trial results we have received to date;
- our plans and expectations for initiating development of avacincaptad pegol for the treatment of intermediate AMD;
- our plans and strategy for the potential commercialization of avacincaptad pegol, 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 avacincaptad pegol and our other product candidates, including scale up and validation of the manufacturing process for avacincaptad pegol 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 avacincaptad pegol drug substance and drug product for our expected needs;
- our plans for evaluating, obtaining rights to, developing and potentially commercializing new formulations of avacincaptad pegol with the silica-based sustained release technology we in-licensed from DelSiTech Ltd. (DelSiTech) and other sustained release delivery technologies for avacincaptad pegol;
- the timing, costs, conduct and outcome of STAR, our ongoing Phase 2b screening trial evaluating avacincaptad pegol for the treatment of autosomal recessive Stargardt disease, including expectations regarding the recruitment of additional patients for this trial;
- our plans and ability to consummate business development transactions, including potential collaboration opportunities for further development and potential commercialization of avacincaptad pegol outside the United States and potential collaboration or outlicense opportunities for further development of IC-100 and IC-200; and in-licenses or other opportunities to acquire rights to additional product candidates or technologies to treat retinal diseases, including additional sustained release delivery technologies for avacincaptad pegol;
- the actual and expected effects of the COVID-19 pandemic, other macro-economic events and related response measures on our business and operations, including the timing, costs, conduct and outcome of our research and development programs, our supply chain, the work of our third-party vendors and collaborators, the work and well-being of our employees, and our financial position;
- 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;

- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and marketing and distribution arrangements;
- the timing, costs, conduct and outcome of our ongoing and planned 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 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 this Quarterly Report on Form 10-Q, particularly in the “Summary of Principal Risk Factors” below and the risk factors detailed further in Item 1A, “Risk Factors”, of Part II of this Quarterly Report on Form 10-Q, that 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.

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.

Summary of Principal Risk Factors

The following is a summary of the principal factors that make an investment in our company speculative or risky. This summary does not address all of the risks and uncertainties that we face. Additional risk and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this summary, and other risks that we face, can be found in Item 1A. "Risk Factors" of Part II of this Quarterly Report on Form 10-Q, and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities Exchange Commission, before making an investment decision regarding our common stock. The forward-looking statements discussed above are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

1. We are a development-stage company without any commercial products. The value of your investment is highly dependent on the success and potential commercialization of avacincaptad pegol. We are working to transition to being a company capable of commercializing a pharmaceutical product, if approved, and may not be successful in this transition.

2. We have a history of significant operating losses and expect to continue to incur losses until we can successfully commercialize one or more of our product candidates, if ever. We may never achieve or maintain profitability.

3. We may need additional financing in order to finish developing and start commercializing one or more of our product candidates, if approved. Securing financing may be challenging and/or dilutive to our shareholders, and if we are unable to secure financing when needed, we may need to curtail our development programs or planned commercialization activities.

4. The covenants in our loan and security agreement with Hercules Capital, Inc. and Silicon Valley Bank may limit and restrict from us from pursuing certain operating activities. If we are in default under that agreement, we may need to repay all existing indebtedness under that term loan facility.

5. The COVID-19 pandemic has adversely affected our business, for example, by impacting the initiation and conduct of our clinical trials, the work of our contract manufacturing organizations, contract research organizations and other vendors, and aspects of our supply chain. Because of the ongoing and fluid nature of the pandemic, it may continue to affect our business.

6. We need to satisfy numerous regulatory requirements in order to secure marketing approval and reimbursement approval, if applicable, for avacincaptad pegol and other product candidates. These requirements differ across jurisdictions. Failure to satisfy and maintain those requirements can preclude us from commercializing our products.

7. Regulatory authorities, including the FDA and EMA, may disagree with the design of or our analyses or conclusions from our clinical trials of avacincaptad pegol in GA secondary to AMD. Since receipt of the 12-month results from GATHER1, we have not had any formal interactions with the EMA regarding our planned regulatory pathway for avacincaptad pegol in GA and the EMA and other regulatory authorities may disagree with the requirements of the FDA. We may need to conduct additional clinical trials or nonclinical studies for avacincaptad pegol in order to obtain marketing approval or reimbursement approval.

8. Manufacturing our product candidates is technically complex, expensive and time consuming. We may face issues with scaling up and validating the manufacturing process for avacincaptad pegol. We may not be able to secure adequate supply of PEG starting material, avacincaptad pegol drug substance or avacincaptad pegol drug product for our future needs, including potential commercial launch. Issues with manufacturing can derail the further development or commercialization of our product candidates.

9. To commercialize any of our product candidates, if approved, we will need to set up a sales and marketing infrastructure. We are continuing to hire commercialization personnel and will need to continue building our commercial infrastructure. The success of our commercialization efforts will depend in part on the degree of acceptance of our product candidates by patients, the medical community and payors.

10. We face substantial competition from large pharmaceutical companies, smaller biotech companies and others.

11. Drug development is inherently risky with numerous scientific, technical, regulatory and other challenges. A promising drug candidate can fail at any time and for any number of reasons.

12. We are pursuing the development of our product candidates using novel mechanisms of action targeting indications for which there are no approved products. These include, for example, complement inhibition and inhibition of High temperature requirement A serine peptidase 1 protein for GA, and complement inhibition for intermediate AMD and autosomal recessive Stargardt disease. These approaches carry numerous scientific, regulatory and other risks.

13. The 12-month results of GATHER2 may not be replicated by the 24-month results from the trial, which may not replicate the results of the GATHER1 trial. We may discover safety issues with our product candidates due to known and currently unknown factors, which could hamper their further development or commercialization.

14. We may not be successful in developing a formulation of avacincaptad pegol with the sustained release delivery technology we in-licensed from DelSiTech, or obtaining rights to and developing other sustained release delivery technologies for avacincaptad pegol.

15. We do not have any internal manufacturing facilities and rely heavily on our third-party contract manufacturers. They may have different business priorities than we do and may fail to meet our expectations or follow regulatory requirements, including current good manufacturing practices and data integrity requirements. We may need to engage alternative manufacturers or suppliers sooner than we currently expect.

16. We plan to rely on third-party distribution and other commercial services vendors to assist us with the commercialization of avacincaptad pegol, if approved, and those third parties may not perform satisfactorily for any number of reasons.

17. We rely heavily on our third-party contract research organizations as well as our clinical trial sites. They may have different priorities than we do and may fail to follow regulatory requirements, including good laboratory practice, good clinical practice and other data integrity requirements.

18. We may pursue a collaboration for the further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States, and are seeking a collaborator or licensee for the further development and potential commercialization of IC-100 and IC-200. For any of these, we may not be able to enter into a collaboration or out-license on favorable terms, or at all. Even if we are able to do so, the collaboration or out-license may not be successful.

19. We rely on patents to protect our proprietary position. We may not obtain the patent rights that we seek and/or we may not be able to exclude our competitors from relevant markets. We may be subject to litigation involving our patents or those of third parties.

20. We are highly dependent on our information security systems and those of third parties we work with. A cybersecurity incident may cause interruptions to the progress of our development programs and operations, financial or regulatory penalties and/or harm to our reputation.

21. We rely on a limited number of employees to conduct our operations, including supervising our outside vendors. The skills needed to advance our research and development programs and plan for commercialization of our product candidates are highly specialized. We plan to hire additional qualified personnel, including sales force personnel, to support the growth of our business. Hiring these personnel and retaining existing employees may be challenging.

22. We and any potential commercialization partners are subject to numerous healthcare laws and regulations governing our relationships with patients, healthcare professionals and third-party payors. Failure to comply with these requirements may adversely affect our business.

23. The reimbursement and payment regime for pharmaceutical products in the United States remains in flux, including as a result of the implementation of and litigation involving the Patient Protection and Affordable Care Act. There are ongoing, and often bipartisan, efforts to reduce the prices of pharmaceutical products.

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)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 153,100	$ 261,447
Available for sale securities	167,435	120,302
Prepaid expenses and other current assets	8,943	5,739
Total current assets	329,478	387,488
Property and equipment, net	708	348
Right-of-use asset, net	1,604	1,522
Total assets	$ 331,790	$ 389,358
Liabilities and Stockholders' Equity		
Current liabilities		
Accrued research and development expenses	$ 11,383	$ 14,403
Accounts payable and accrued expenses	11,601	12,856
Lease liability	1,604	952
Total current liabilities	24,588	28,211
Lease liability, non-current	27	619
Term loan, net	47,649	—
Total liabilities	72,264	28,830
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, 120,572,641 and 115,277,012 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	121	115
Additional paid-in capital	1,065,545	1,040,098
Accumulated deficit	(805,745)	(679,595)
Accumulated other comprehensive income	(395)	(90)
Total stockholders' equity	259,526	360,528
Total liabilities and stockholders' equity	$ 331,790	$ 389,358

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 24,967	$ 17,935	$ 81,171	$ 59,972
General and administrative	17,545	6,648	45,764	21,688
Total operating expenses	42,512	24,583	126,935	81,660
Loss from operations	(42,512)	(24,583)	(126,935)	(81,660)
Interest income, net	200	42	815	184
Other expense, net	(39)	(10)	(30)	(13)
Loss before income tax benefit	(42,351)	(24,551)	(126,150)	(81,489)
Income tax benefit	—	—	—	—
Net loss	$ (42,351)	$ (24,551)	$ (126,150)	$ (81,489)
Comprehensive loss	$ (42,218)	$ (24,565)	(126,455)	$ (81,503)
Net loss per common share:				
Basic and diluted	$ (0.35)	$ (0.23)	(1.05)	$ (0.84)
Weighted average common shares outstanding:				
Basic and diluted	120,277	105,217	119,578	97,370

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, 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
Issuance of common stock under employee stock compensation plans	—	—	900	1	2,800	—	—	2,801
Share-based compensation	—	—	—	—	6,388	—	—	6,388
Net loss	—	—	—	—	—	(49,263)	—	(49,263)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	(134)	(134)
Balance at June 30, 2022	—	$ —	116,874	$ 117	$ 1,056,751	$ (763,394)	$ (528)	$ 292,946
Issuance of common stock under employee stock compensation plans and warrants	—	—	3,698	4	2,238	—	—	2,242
Share-based compensation	—	—	—	—	6,556	—	—	6,556
Net loss	—	—	—	—	—	(42,351)	—	(42,351)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	133	133
Balance at September 30, 2022	—	$ —	120,572	$ 121	$ 1,065,545	$ (805,745)	$ (395)	$ 259,526

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	$ —	90,121	$ 90	$ 756,543	$ (565,073)	$ 3	$ 191,563
Issuance of common stock under employee stock compensation plans	—	—	49	—	129	—	—	129
Share-based compensation	—	—	—	—	2,292	—	—	2,292
Net loss	—	—	—	—	—	(26,795)	—	(26,795)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	(1)	(1)
Balance at March 31, 2021	—	$ —	90,170	$ 90	$ 758,964	$ (591,868)	$ 2	$ 167,188
Issuance of common stock under employee stock compensation plans	—	—	217	—	448	—	—	448
Share-based compensation	—	—	—	—	2,079	—	—	2,079
Net loss	—	—	—	—	—	(30,143)	—	(30,143)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	1	1
Balance at Balance at June 30, 2021	—	$ —	90,387	$ 90	$ 761,491	$ (622,011)	$ 3	$ 139,573
Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs	—	—	13,398	14	107,743	—	—	107,757
Issuance of common stock under employee stock compensation plans	—	—	453	—	1,095	—	—	1,095
Share-based compensation	—	—	—	—	2,626	—	—	2,626
Net loss	—	—	—	—	—	(24,551)	—	(24,551)
Unrealized loss on available for sale securities, net of tax	—	—	—	—	—	—	(14)	(14)
Balance at Balance at September 30, 2021	—	$ —	104,238	$ 104	$ 872,955	$ (646,562)	$ (11)	$ 226,486

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

IVERIC bio, Inc.

Condensed Unaudited Consolidated Statements of Cash Flows

(in thousands)

	Nine Months Ended September 30,	
	2022	2021
Operating Activities		
Net loss	$ (126,150)	$ (81,489)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and other expense	80	24
Amortization and accretion of term loan related costs	172	—
Amortization of premium and discounts on investment securities	450	918
Share-based compensation	18,330	6,997
Changes in operating assets and liabilities:		
Income tax receivable	—	1,765
Prepaid expense and other assets	(3,204)	726
Accrued interest receivable	82	449
Accrued research and development expenses	(3,020)	(916)
Accounts payable and accrued expenses	(1,660)	(4,662)
Accrued interest payable	405	—
Change in working capital	(22)	63
Net cash used in operating activities	(114,537)	(76,125)
Investing Activities		
Purchase of marketable securities	(165,469)	(56,245)
Purchase of property and equipment	(440)	—
Maturities of marketable securities	117,499	136,447
Net cash (used in) provided by investing activities	(48,410)	80,202
Financing Activities		
Proceeds from employee stock plan purchases	7,123	1,672
Proceeds from term loan	50,000	—
Payment of term loan issuance costs	(2,523)	—
Proceeds from follow-on public offering, net	—	107,757
Net cash provided by financing activities	54,600	109,429
Net increase (decrease) in cash and cash equivalents	(108,347)	113,506
Cash and cash equivalents		
Beginning of period	261,447	66,373
End of period	$ 153,100	$ 179,879
Supplemental disclosure of cash paid		
Income tax refunds received	$ —	$ 1,765
Supplemental disclosures of non-cash information related to investing and financing activities		
Operating right-of-use assets obtained in exchange for lease obligations	$ 953	$ 2,086
“Interest expense” paid in cash	$ 486	$ —

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").

The Company's lead asset is its clinical stage product candidate avacincaptad pegol (also referred to as Zimura®), 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 that precedes GA; 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.

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. The Company

recently submitted to the FDA the first part of its NDA, which includes the complete clinical data package for avacincaptad pegol, for rolling review of avacincaptad pegol for the treatment of GA secondary to AMD. The Company plans to complete the submission of the NDA to the FDA by the end of 2022.

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 two preclinical stage gene therapy product candidates (IC-100 and IC-200) and 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"):

- rhodopsin-mediated autosomal dominant retinitis pigmentosa ("RHO-adRP"), which is characterized by progressive and severe bilateral loss of vision leading to blindness;
- IRDs associated with mutations in the BEST1 gene, including Best vitelliform macular dystrophy ("Best disease");
- 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.

As the Company focuses its efforts on and prioritizes the development and potential commercialization of avacincaptad pegol, it has been considering its development options for IC-100 and IC-200, which the Company has been developing for RHO-adRP and BEST1-related IRDs, respectively. It is currently seeking a collaborator or licensee for the future development and potential commercialization of these product candidates.

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, 2021 filed with the Securities and Exchange Commission ("SEC") on February 24, 2022.

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 nine months ended September 30, 2022 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 reportable 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.

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.

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

The Company's financial instruments that are exposed to concentration of credit risk consist primarily 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. 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.

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 and one additional third-party manufacturer to provide fill/finish services for avacincaptad pegol drug product. 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 GMP 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.

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 asset includes 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 academic research collaborators, 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, non-employees 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, non-employee directors and consultants 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 and nine month periods ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Expected common stock price volatility	76%	113%	83%	113%
Risk-free interest rate	2.64%-3.36%	0.68%-0.84%	1.38%-3.36%	0.31%-0.96%
Expected term of options (years)	5.0	5.2	4.9	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 months 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 September 30, 2022, the Company had no pre-funded warrants outstanding. As of September 30, 2021, the Company had 3,164,280 pre-funded warrants outstanding, which if exercised, would increase the number of shares of common stock issued and 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Basic and diluted net loss per common share calculation:				
Net loss	$ (42,351)	$ (24,551)	$ (126,150)	$ (81,489)
Weighted average common shares outstanding - basic and dilutive	120,277	105,217	119,578	97,370
Net loss per share of common stock - basic and diluted	$ (0.35)	$ (0.23)	$ (1.05)	$ (0.84)

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options outstanding	10,250	9,089	10,250	9,089
Restricted stock units	2,401	1,903	2,401	1,903
Total	12,651	10,992	12,651	10,992

4. Licensing and Commercialization Agreements

On June 30, 2022, the Company entered into a license agreement (the "DelSiTech License Agreement") with DelSiTech Ltd. ("DelSiTech"). Under the DelSiTech License Agreement, DelSiTech granted the Company a worldwide, exclusive license under specified patent rights and know-how to develop, have developed, make, have made, use, offer to sell, sell, have sold, otherwise commercialize, export and import avacincaptad pegol using DelSiTech's silica-based sustained release technology for the treatment of diseases of the eye in humans (the "Licensed Product"). The Company may grant sublicenses of the licensed patent rights and know-how without DelSiTech's consent.

The Company has agreed to pay DelSiTech, within 60 days after execution of the DelSiTech License Agreement, a €1.25 million upfront license fee, which was recognized as a research and development expense during the three months ended June 30, 2022. Under the DelSiTech License Agreement, the Company is further obligated to pay DelSiTech, up to an aggregate of €35.0 million, if the Company achieves specified clinical and development milestones with respect to the 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. Due to the uncertainty of the achievement of these milestones, the Company will account for any additional payments if and when such milestones are met.

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. The Company's obligation to pay royalties under the DelSiTech License Agreement will continue on a country-by-country basis until the later of: (a) the expiration of the last-to-expire licensed patent rights covering the Licensed Product in the country of sale, or (b) expiration of all regulatory exclusivity for the Licensed Product in the country of sale. Future milestones and royalties will be recognized in their entirety when achieved.

Unless earlier terminated by the Company or DelSiTech, the DelSiTech License Agreement will expire on a country-by-country basis upon the expiration of the Company's obligation to pay royalties to DelSiTech on net sales of the Licensed Product. Upon expiration of the DelSiTech License Agreement, the licenses granted by DelSiTech to the Company will become fully paid up and irrevocable. The Company may terminate the agreement at any time for any reason upon 60 days' prior written notice to DelSiTech. Either party may also terminate the DelSiTech License Agreement if the other party materially breaches the DelSiTech License Agreement and does not cure such breach within a specified cure period. Following any termination of the DelSiTech License Agreement prior to expiration of the term of the DelSiTech License Agreement, all rights to the licensed patent rights and know-how that DelSiTech granted to the Company will revert to DelSiTech, subject to the Company's right to sell off any Licensed Product in the Company's inventory as of the effectiveness of such termination.

5. 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 September 30, 2022 and December 31, 2021, the Company had cash and cash equivalents of approximately $153.1 million and $261.4 million, respectively. Cash and cash equivalents included cash of $9.9 million at September 30, 2022 and $9.9 million at December 31, 2021. Cash and cash equivalents at September 30, 2022 and December 31, 2021 included $143.2 million and $251.5 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 September 30, 2022 and December 31, 2021, the Company held available for sale securities of $167.4 million and $120.3 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 September 30, 2022. 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 September 30, 2022 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 September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 48,001	$ —	$ (183)	$ 47,818
Corporate debt securities	100,383	—	(172)	100,211
Asset-backed securities	14,472	1	(37)	14,436
Supranational securities	4,974	—	(4)	4,970
Total	$ 167,830	$ 1	$ (396)	$ 167,435

	As of December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 18,201	$ —	$ (16)	$ 18,185
Corporate debt securities	82,138	—	(57)	82,081
Asset-backed securities	16,009	—	(14)	15,995
Supranational securities	4,044	—	(3)	4,041
Total	$ 120,392	$ —	$ (90)	$ 120,302

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 September 30, 2022 and 2021, respectively, were as follows:

	Three months ended September 30,		Nine Months Ended September 30, 2022	
	2022	2021	2022	2021
Beginning balance	$ (528)	$ 3	$ (90)	$ 3
Current period changes in fair value before reclassifications, net of tax	133	(14)	(305)	(14)
Amounts reclassified from accumulated other comprehensive income, net of tax	—	—	—	—
Total other comprehensive loss	$ 133	$ (14)	(305)	(14)
Ending balance	$ (395)	$ (11)	$ (395)	$ (11)

6. 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 September 30, 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*	$ 143,165	$ —	$ —
Investments in U.S. Treasury securities	$ 47,818	$ —	$ —
Investments in corporate debt securities	$ —	$ 100,211	$ —
Investments in asset-backed securities	$ —	14,436	$ —
Investments in supranational securities	$ —	4,970	$ —

* 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, 2021:

	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*	$ 251,488	$ —	$ —
Investments in U.S. Treasury securities	$ 18,185	$ —	$ —
Investments in corporate debt securities	$ —	$ 82,081	$ —
Investments in asset-backed securities	$ —	$ 15,995	$ —
Investments in supranational securities	$ —	$ 4,041	$ —

* 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 and nine months ended September 30, 2022.

7. 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 15,624,000 additional shares to the 2013 Plan, including for 2022, an increase of approximately 2,542,000 shares. As of September 30, 2022, the Company had approximately 3,204,000 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, the Company's board of directors amended the 2019 Inducement Plan to reserve an additional 1,000,000 shares of its common stock for issuance under the plan, and in February 2021, September 2021, December 2021 and May 2022, the Company's board of directors further amended the 2019 Inducement Plan to reserve an additional 600,000 shares, an additional 1,000,000 shares, an additional 1,000,000 shares and an additional 1,000,000 shares, respectively, of its common stock for issuance under the plan. As of September 30, 2022, the Company had approximately 1,245,000 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	$ 4,021	$ 1,485	$ 11,095	$ 3,997
Restricted stock units	2,444	1,101	7,020	2,896
Employee stock purchase plan	91	40	215	104
Total	$ 6,556	$ 2,626	$ 18,330	$ 6,997

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 2,681	$ 1,476	$ 8,108	$ 4,138
General and administrative	3,875	1,150	10,222	2,859
Total	$ 6,556	$ 2,626	$ 18,330	$ 6,997

Stock Options

A summary of the stock option activity, weighted average exercise prices, options outstanding, exercisable and expected to vest as of September 30, 2022 is as follows (in thousands except weighted average exercise price):

	Number of Shares Underlying Options	Weighted Average Exercise Price
Outstanding, December 31, 2021	10,861	$ 10.94
Granted	1,388	$ 14.23
Exercised	(1,797)	$ 3.69
Forfeited	(202)	$ 14.14
Outstanding, September 30, 2022	10,250	$ 12.60
Vested and exercisable, September 30, 2022	4,830	$ 13.38
Vested and expected to vest, September 30, 2022	9,762	$ 12.63

As of September 30, 2022, there were approximately $37.4 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 2.9 years.

RSUs

The following table presents a summary of the Company's outstanding RSU awards granted as of September 30, 2022 (in thousands except weighted average grant-date fair value):

	Restricted Stock Units	Weighted Average Grant-Date Fair Value
Outstanding, December 31, 2021	2,246	$ 9.82
Awarded	494	$ 11.79
Vested	(293)	$ 8.32
Forfeited	(46)	$ 10.95
Outstanding, September 30, 2022	2,401	$ 10.39
Outstanding, expected to vest	2,185	$ 10.39

As of September 30, 2022, there were approximately $16.8 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 2.5 years.

ESPP

As of September 30, 2022, there were 712,394 shares available for future purchases under the ESPP. There were 25,921 and 27,529 shares issued under the ESPP during the three months ended September 30, 2022 and 2021, respectively. There were 41,016 and 51,951 shares of common stock issued under the ESPP during the nine months ended September 30, 2022 and 2021, respectively. Cash proceeds from ESPP purchases were $331 thousand and $146 thousand during the three months ended September 30, 2022 and 2021, respectively. Cash proceeds from ESPP purchases were $515 thousand and $266 thousand during the nine months ended September 30, 2022 and 2021, respectively.

8. 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 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.

IC-100 - University of Florida and the University of Pennsylvania

Under its exclusive license agreement with the University of Florida Research Foundation, Incorporated (“UFRF”) and the University of Pennsylvania (“Penn”) for rights to IC-100, the Company is obligated to make payments to UFRF, for the benefit of Penn and UFRF (together, the “Licensors”), of up to an aggregate of $23.5 million if the Company achieves specified clinical, marketing approval and reimbursement approval milestones with respect to a licensed product and up to an aggregate of an additional $70.0 million if the Company achieves specified commercial sales milestones with respect to a licensed product. The Company is also obligated to pay UFRF, for the benefit of the Licensors, a low single-digit percentage of net sales of licensed products. The Company is also obligated to pay UFRF, for the benefit of the Licensors, a double-digit percentage of specified non-royalty payments the Company may receive from any third-party sublicensee of the licensed patent rights. Further, if the Company receives a rare pediatric disease 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, the Company will be obligated to pay UFRF, for the benefit of the Licensors, aggregate payments in the low double-digit millions of dollars based on certain approval and commercial sales milestones with respect to such other product candidate. In addition, if the Company sells such a priority review voucher to a third party, the Company will be obligated to pay UFRF, for the benefit of the Licensors, a low double-digit percentage of any consideration received from such third party in connection with such sale.

IC-200 - University of Pennsylvania and the University of Florida

Under its exclusive license agreement with Penn and UFRF for rights to IC-200, the Company is obligated to make payments to Penn, for the benefit of the Licensors, of up to an aggregate of $15.7 million if the Company achieves specified clinical, marketing approval and reimbursement approval milestones with respect to one licensed product and up to an aggregate of an additional $3.1 million if the Company achieves these same milestones with respect to a different licensed product. In addition, the Company is obligated to make payments to Penn, for the benefit of the Licensors, of up to an aggregate of $48.0 million if the Company achieves specified commercial sales milestones with respect to one licensed product and up to

an aggregate of an additional $9.6 million if the Company achieves these same milestones with respect to a different licensed product. The Company is also obligated to pay Penn, for the benefit of the Licensors, a low single-digit percentage of net sales of licensed products. The Company is also obligated to pay Penn, for the benefit of the Licensors, a high single-digit to a mid-teen percentage of specified non-royalty payments the Company may receive from any third-party sublicensee of the licensed patent rights, with the applicable percentage based upon the stage of development of the sublicensed product at the time the Company enters into the sublicense. Further, if the Company receives a rare pediatric disease 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 Penn, for the benefit of the Licensors, aggregate payments in the low double-digit millions of dollars based on certain approval and commercial sales milestones with respect to such other product candidate. In addition, if the Company sells such a priority review voucher to a third party, the Company will be obligated to pay Penn, for the benefit of the Licensors, a high single-digit percentage of any consideration received from such third party in connection with such sale.

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 Equity holders 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 equity holders 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 equity holders 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 in connection with a change in control or termination of employment by the employee for good reason or by the Company without cause, 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 and manufacturing activities. Expenditures to CROs and

CDMOs represent significant costs in preclinical and clinical development. 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.

Legal Proceedings

On January 11, 2017, a putative class action lawsuit was filed against the Company and certain of its current and former executive officers in the United States District Court for the Southern District of New York, captioned Frank Micholle v. Ophthotech Corporation, et al., No. 1:17-cv-00210. On March 9, 2017, a related putative class action lawsuit was filed against the Company and the same group of its current and former executive officers in the United States District Court for the Southern District of New York, captioned Wasson v. Ophthotech Corporation, et al., No. 1:17-cv-01758. These cases were consolidated on March 13, 2018. On June 4, 2018, the lead plaintiff filed a consolidated amended complaint (the "CAC"). The CAC purports to be brought on behalf of shareholders who purchased the Company's common stock between March 2, 2015 and December 12, 2016. The CAC generally alleges that the Company and certain of its officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the results of the Company's Phase 2b trial and the prospects of the Company's Phase 3 trials for Fovista in combination with anti-VEGF agents for the treatment of wet AMD. The CAC seeks unspecified damages, attorneys' fees, and other costs. The Company and individual defendants filed a motion to dismiss the CAC on July 27, 2018. On September 18, 2019, the court issued an order dismissing some, but not all, of the allegations in the CAC. On November 18, 2019, the Company and the individual defendants filed an answer to the complaint. On June 12, 2020, the lead plaintiff filed a motion for class certification. On August 11, 2020, the defendants filed a notice of non-opposition to lead plaintiff's motion for class certification. On April 23, 2021, the court issued an order staying the action until July 1, 2021, 10 days after a mediation scheduled for June 21, 2021. On July 1, 2021, following the June 21, 2021 mediation, the parties notified the court that they had reached an agreement in principle to settle the class action. On September 8, 2021, the parties executed a settlement agreement and submitted the agreement to the court for approval. Under the terms of the settlement agreement, the Company agreed to pay $29 million, which includes the attorneys' fees and costs and expenses for the plaintiffs' counsel. On March 17, 2022, the court provided a preliminary approval of the settlement. In April 2022, the Company's insurance carriers paid the full amount of the settlement directly to the plaintiffs' escrow account. On September 16, 2022, the court granted final approval of the settlement. This settlement did not have a material impact on the Company's financial condition.

On August 31, 2018, a shareholder derivative action was filed against current and former members of the Company's board of directors and certain current and former officers of the Company in the United States District Court for the Southern District of New York, captioned Luis Pacheco v. David R. Guyer, et al., Case No. 1:18-cv-07999. The complaint, which is based substantially on the facts alleged in the CAC, alleges that the defendants breached their fiduciary duties to the Company and wasted the Company's corporate assets by failing to oversee the Company's business, and also alleges that the defendants were unjustly enriched as a result of the alleged conduct, including through receipt of bonuses, stock options and similar compensation from the Company, and through sales of the Company's stock between March 2, 2015 and December 12, 2016. The complaint purports to seek unspecified damages on the Company's behalf, attorneys' fees, and other costs, as well as an order directing the Company to reform and improve its corporate governance and internal procedures to comply with applicable laws, including submitting certain proposed amendments to the Company's corporate charter, bylaws and corporate governance policies for vote by the Company's stockholders. On December 14, 2018, the Company filed a motion to dismiss the complaint. On September 19, 2019, the court denied its motion to dismiss this complaint. This matter was subsequently referred to a special litigation committee ("SLC") of the Company's board of directors. On February 18, 2020, the Company filed an answer to the complaint. The Company and the plaintiff agreed to stay this litigation while the SLC conducts its investigation. On May 4, 2020, the court approved the stipulation and stayed the litigation through November 1, 2020. By agreement of the parties, the court has since extended the stay through June 26, 2021. The Company also entered into tolling agreements with the defendant directors to December 2022. On January 27, 2022, the parties executed a settlement agreement (the "Stipulation of Settlement"). On November 3, 2022, the court issued an order preliminarily approving the settlement. Copies of the Stipulation of Settlement and Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions are attached as Exhibits 99.1 and 99.2 to this Quarterly Report on Form 10-Q. The Company does not expect this settlement, if granted final approval in its current form, to have a material impact on its financial condition.

On October 16, 2018, the Company's board of directors received a shareholder demand to investigate and commence legal proceedings against certain members of the Company's board of directors. The demand alleges facts that are substantially similar to the facts alleged in the CAC and the Pacheco complaint and asserts claims that are substantially similar to the claims asserted in the Pacheco complaint. On January 30, 2019, the Company's board of directors received a second shareholder demand from a different shareholder to investigate and commence legal proceedings against certain current and former members of the Company's board of directors based on allegations that are substantially similar to the allegations contained in the first demand letter. These shareholder demands were referred to a demand review committee of the Company's board of directors. On May 6, 2021, the shareholders who served the October 16, 2018 demand filed a shareholder derivative action

against current and former members of the Company's board of directors and certain current and former officers of the Company in the New York Supreme Court, captioned Brian Ferber et al., derivatively on behalf of Ophthotech Corporation v. Axel Bolte et al., Index No. 154462/2021. The complaint asserts the same claims as those asserted in the Pacheco complaint and is based on factual allegations that are materially similar to the allegations in the Pacheco complaint. On June 22, 2021, the parties filed a stipulation staying the Ferber action until 60 days after the SLC concludes its investigation. The Company has entered into tolling agreements with the directors named in the demands to December 2022. On January 27, 2022, the parties executed a settlement agreement.

The Company denies any and all allegations of wrongdoing and intends to vigorously defend against these lawsuits. The Company is unable, however, to predict the outcome of these matters, including that of the settlement agreement discussions, at this time. Moreover, any conclusion of these matters in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by the Company's directors' and officers' liability insurance would have a material adverse effect on its financial condition and business. In addition, the litigation could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of its business plan and strategies that are important to the Company's ability to grow its business, any of which could have a material adverse effect on the Company's business.

9. Operating Leases

The Company leases office space located in Cranbury, New Jersey and Parsippany, New Jersey under non-cancelable operating lease arrangements. In May 2022, the Company amended its Cranbury office space lease to extend the lease period by one year through the end of February 2024.

In addition, in 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 and nine months ended September 30, 2022, lease expense was $0.4 million and $0.9 million, respectively. Cash paid from operating cash flows for amounts included in the measurement of lease liabilities was $0.5 million and $0.9 million, respectively, for the three and nine months ended September 30, 2022. At September 30, 2022, the Company's operating leases had a weighted average remaining lease term of 0.9 years.

The following presents the maturity of the Company's operating lease liabilities as of September 30, 2022:

Remainder of 2022	451
2023	1,216
2024	11
Total remaining obligation	1,678
Less imputed interest	(47)
Present value of lease liabilities	1,631

10. Loan and Security Agreement

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 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; (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 1 and plans to borrow the full $50.0 million tranche that is available during the fourth quarter of 2022. With the exception of the first $50.0 million tranche drawn on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at the Company's election. 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. 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 the Closing Date, 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 and nine months ended September 30, 2022, 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 September 30, 2022	Nine Months Ended September 30, 2022
Interest expense for term loan	$ 891	$ 891
Accretion of end of term charge	71	71
Amortization of debt issuance costs	101	101
Total interest expense related to term loan	$ 1,063	$ 1,063

The principal balance of this term loan and related accretion and amortization as of September 30, 2022, were as follows:

	September 30, 2022
Term loan, gross (amount drawn)	$ 50,000
Debt issuance costs (legal and other administrative fees)	(2,523)
Accretion of end of term charge	71
Accumulated amortization of debt issuance costs	101
Term loan, net	$ 47,649

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, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 24, 2022. 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 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.

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 Zimura®, a complement C5 inhibitor. We are currently targeting the following diseases with avacincaptad pegol:

- 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 that precedes GA; 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 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. We 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, or FDA, preferred primary efficacy endpoint analysis from 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 avacincaptad pegol 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 avacincaptad pegol 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 avacincaptad pegol 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 avacincaptad pegol 2 mg group and 9 patients (4.1%) in the sham control group.

We believe that with the statistically significant results from our GATHER1 and GATHER2 trials and the safety profile of avacincaptad pegol to date, we have 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. We recently submitted to the FDA the first part of our NDA, which includes the complete clinical data package for avacincaptad pegol, for rolling review of avacincaptad pegol for the treatment of GA secondary to AMD. We plan to complete the submission of the NDA to the FDA by the end of 2022.

In addition to avacincaptad pegol, 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.

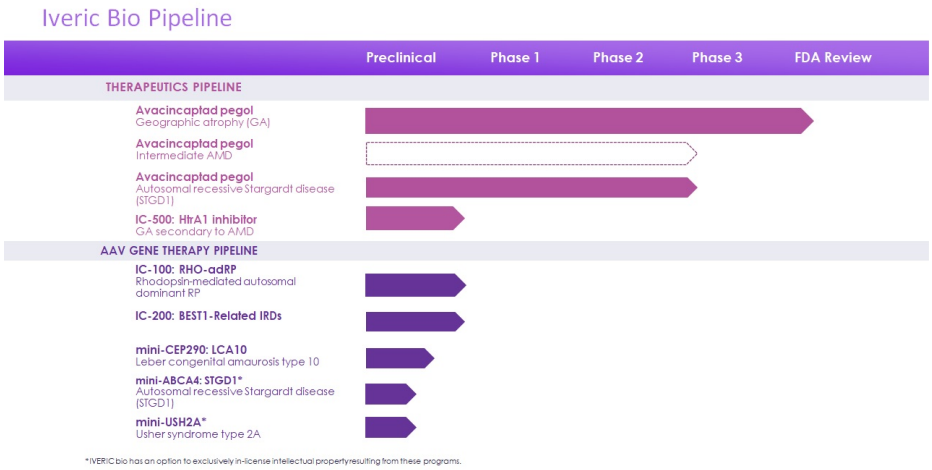
Our portfolio also includes two preclinical stage gene therapy product candidates (IC-100 and IC-200) and several ongoing gene therapy research programs, each of which uses adeno-associated virus, or AAV, for gene delivery. These AAV mediated gene therapy programs are targeting the following orphan inherited retinal diseases, or IRDs:

- rhodopsin-mediated autosomal dominant retinitis pigmentosa, or RHO-adRP, which is characterized by progressive and severe bilateral loss of vision leading to blindness;
- IRDs associated with mutations in the BEST1 gene, including Best vitelliform macular dystrophy, or Best disease;
- 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.

As we focus our efforts on and prioritize the development and potential commercialization of avacincaptad pegol, we have been considering our development options for IC-100 and IC-200, which we have been developing for RHO-adRP and BEST1-related IRDs, respectively. We are currently seeking a collaborator or licensee for the future development and potential commercialization of these product candidates.

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 our clinical development programs for avacincaptad pegol, our manufacturing activities for avacincaptad pegol and our lifecycle management initiatives for avacincaptad pegol.

GATHER2 (GA secondary to AMD - Ongoing)

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. In September 2022, we announced 12-month top-line data from this trial.

Trial Design

We enrolled 448 patients who were randomized to receive either monthly administration of avacincaptad pegol 2 mg or sham during the first 12 months of the trial. At month 12, patients in the avacincaptad pegol 2 mg arm are re-randomized to receive either monthly or every other month administration of avacincaptad pegol 2 mg and patients receiving monthly administrations of sham continue to receive monthly administrations of sham. The final evaluation for patients will take place at month 24.

We recently initiated an open-label extension study for patients who completed the GATHER2 trial; information about this study is described further below.

Baseline Characteristics

We collected baseline characteristics for all patients participating in the GATHER2 trial, which are presented below for each treatment group. These baseline characteristics include the intent-to-treat, or ITT, population, which includes all patients who were randomized in the trial and who received at least one dose of study drug in the relevant treatment group. For patients within each treatment group, where a numerical measurement was collected, we calculated the mean and standard deviation, or SD, for each measurement. SD is a statistical measure of the variability of a particular measurement within a patient population. Generally, two-thirds of all patients fall within approximately one SD, plus or minus, of the mean for any

particular measurement. Based on these data, we believe that the baseline characteristics were balanced across the treatment groups.

	Treatment Group	
Baseline Characteristic	**Avacincaptad Pegol 2 mg** (N = 225)	**Sham** (N = 222)
Mean age, years (SD)	76.3 (8.6)	76.7 (8.8)
Female gender, number (%)	154 (68.4%)	156 (70.3%)
Active smokers, number (%)	106 (47.1%)	107 (48.2%)
Caucasian race, number (%)	182 (80.9%)	186 (83.8%)
Iris color, number (%):		
Light	93 (41.3%)	109 (49.1%)
Medium	96 (42.7%)	79 (35.6%)
Dark	36 (16.0%)	34 (15.3%)
Mean intraocular pressure, mmHg (SD)	15.2 (2.5)	14.9 (2.6)
Non-subfoveal GA, number (%)	225 (100%)	222 (100%)
Multifocal GA, number (%)	178 (79.1%)	178 (80.2%)
GA size of greater than or equal to 4 disc areas, number (%)	54 (24.0%)	64 (28.8%)
Mean GA area, mm^2 (SD)	7.48 (4.01)	7.81 (3.89)
Mean Sq. Root of GA area, mm (SD)	2.641 (0.714)	2.707 (0.696)
Bilateral GA, number (%)	212 (94.0%)	210 (95.0%)
Mean BCVA, ETDRS letters (SD)	70.9 (8.9)	71.6 (9.4)
Mean LL BCVA, ETDRS letters (SD)	41.0 (19.7)	39.6 (19.6)
Patients with Hyperautofluorscence - Banded/Diffuse, number (%)	217 (96.4%)	218 (98.2%)
Height, cm (SD)	164.6 (10.6)	164.0 (9.4)
Weight, kg (SD)	75.9 (18.3)	75.0 (15.8)

12-Month Safety Data

In GATHER2, there were no events of endophthalmitis, no intraocular inflammation events, no events of vasculitis and no ischemic optic neuropathy events through month 12. The most frequently reported ocular adverse events were related to the injection procedure, including transient intraocular pressure.

The incidence of 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. An independent masked reading center assessed the CNV cases in GATHER2 at the 12-month timepoint for exudative macular neovascularization, or eMNV, and non-exudative macular neovascularization, or neMNV. Please reference our Current Report on Form 8-K filed on April 4, 2022 for the CNV assessment criteria.

The following tables provide further detail on these adverse events of interest, along with the corresponding safety data from the GATHER1 trial at 12 months:

Reported Adverse Events of Interest

	Endophthalmitis	Intraocular Inflammation	Ischemic Optic Neuropathy
GATHER1			
avacincaptad pegol 2 mg (N=67)	0	1*	0
Sham (N = 110)	0	0	0
GATHER2			
avacincaptad pegol 2mg (N=225)	0	0	0
Sham (N=222)	0	0	0

* Transient and mild; reported as related to injection procedure.

Reported Choroidal Neovascularization Cases

	eMNV (%)	neMNV (%)	Peripapillary CNV (%)	Total CNV (%)
GATHER1				
avacincaptad pegol 2 mg (N=67)	4 (6.0%)	2 (3.0%)	0	6 (9.0%)
Sham (N = 110)	*	*	*	3 (2.7%)
GATHER2				
avacincaptad pegol 2mg (N=225)	11 (4.9%)	1 (0.5%)	3 (1.3%)	15 (6.7%)
Sham (N=222)	7 (3.2%)	0	2 (0.9%)	9 (4.1%)

* Not available.

The number of patients having treatment emergent adverse events, or TEAEs, organized by MedDRA system organ class, a standard method of reporting adverse events, for which there are two percent or greater of such TEAE among the patients in any treatment group, are set forth in the table below:

Patients with TEAEs in any Organ Class for which TEAE Comprises 2% or Greater of Patients in any Treatment Group

	Treatment Group	
Organ Class	**avacincaptad pegol 2 mg** (N = 225)	**Sham** (N = 222)
Blood and lymphatic system disorders	4 (1.8%)	5 (2.3%)
Cardiac disorders	22 (9.8%)	16 (7.2%)
Ear and labyrinth disorders	1 (0.4%)	5 (2.3%)
Eye disorders	110 (48.9%)	84 (37.8%)
Gastrointestinal disorders	16 (7.1%)	13 (5.9%)
General disorders and administration site conditions	7 (3.1%)	10 (4.5%)
Infections and infestations	59 (26.2%)	58 (26.1%)
Injury, poisoning and procedural complications	36 (16.0%)	32 (14.4%)
Investigations	31 (13.8%)	10 (4.5%)
Metabolism and nutrition disorders	9 (4.0%)	8 (3.6%)
Musculoskeletal and connective tissue disorders	22 (9.8%)	24 (10.8%)
Benign, malignant and unspecified neoplasms (including cysts and polyps)	9 (4.0%)	16 (7.2%)
Nervous system disorders	14 (6.2%)	28 (12.6%)
Psychiatric disorders	6 (2.7%)	4 (1.8%)
Renal and urinary disorders	10 (4.4%)	5 (2.3%)
Respiratory, thoracic and mediastinal disorders	10 (4.4%)	8 (3.6%)
Skin and subcutaneous tissue disorders	8 (3.6%)	10 (4.5%)
Vascular disorders	14 (6.2%)	13 (5.9%)

The number of patients having ocular TEAEs in the study eye for which there are two percent or greater of such TEAE among the patients in any treatment group, are set forth in the table below:

Ocular TEAEs in any Organ Class in Study Eyes for which TEAE Comprises 2% or Greater of Patients in any Treatment Group

	Treatment Group	
Organ Class	**avacincaptad pegol 2 mg** (N = 225)	**Sham** (N = 222)
Eye disorders	104 (46.2%)	80 (36.0%)
Infections and infestations	3 (1.3%)	5 (2.3%)
Injury, poisoning and procedural complications	5 (2.2%)	1 (0.5%)
Investigations	21 (9.3%)	2 (0.9%)

Among the eye disorder ocular TEAEs, two of the TEAEs were reported as serious in the avacincaptad pegol 2 mg group, as compared to three TEAEs in the sham group. In the avacincaptad pegol 2 mg group, both serious TEAEs were cases of CNV. In the sham group, one serious TEAE was a CNV case, one was a case of visual acuity reduced and one was a case of visual acuity reduced transiently.

Among the ocular cases of injury, poisoning and procedural complications, all were procedural complications of intravitreal injection or sham administration. None of these cases were serious.

All 23 ocular investigation cases were cases of increased intraocular pressure, or IOP. None of these cases were serious. Of the 21 cases in the avacincaptad pegol 2 mg group, 20 of them were transient in nature; of the 20 transient cases, 19 of them resolved the same day. The single non-transient case in the avacincaptad pegol 2 mg group was for a patient with glaucoma at baseline. The increased incidence of increased IOP is expected for an intravitreal injection as compared to a sham procedure. Patients in the sham group had a barrel of a syringe placed against the eye to simulate the pressure of an injection but no needle penetrates the eye.

12-Month Efficacy Data

The primary efficacy endpoint, in accordance with our SPA with the FDA, is the mean rate of growth (slope) estimated based on GA area, as measured by FAF based on readings at three timepoints: baseline, month 6 and month 12. The FAF images were assessed by an independent masked reading center. We performed the pre-specified primary analysis of the endpoint by using the square root transformation of the GA area and we performed the pre-specified supportive analysis of the endpoint by using the observed GA area (without square root transformation). Detailed data for the primary efficacy endpoint with both the primary analysis and supportive analysis are shown in the accompanying table:

Mean Rate of Growth (Slope) in GA Area from Baseline to Month 12

MMRM Analysis (mixed model of repeated measures)	**avacincaptad pegol 2 mg (N = 225)**	**Sham (N = 222)**	**Difference**	**% Difference**	**P-Value**
Mean Rate of GA Growth (Slope) (mm) (Square Root Transformation)	0.336	0.392	0.056	14.3%	0.0064
Mean Rate of GA Growth (Slope) (mm^2) (Observed)	1.745	2.121	0.376	17.7%	0.0039

We also analyzed the mean change in GA area from baseline to month 12 in GATHER2 using a point analysis, which was the pre-specified primary efficacy endpoint analysis in GATHER1. This analysis was performed based on FAF readings at the same three time points (baseline, month 6, and month 12) as the slope analyses. The results for the 12-month point analysis were consistent with the slope analyses and are described below.

The following tables show the GATHER1 and GATHER2 efficacy results for both (A) the mean rate of change in GA area from baseline to month 12 using a point analysis and (B) the mean rate of growth (slope) in GA area over 12 months. These results are provided using both the square root transformation and the observed GA areas.

GATHER1

MMRM Analysis	**avacincaptad pegol 2 mg (N = 67)**	**Sham (N = 110)**	**Difference**	**% Difference**	**P-Value**
Sq. Rt. Transformation					
Mean Change in GA Area (mm)	0.292	0.402	0.110	27.4%	0.0072[a]
Mean Rate of GA Growth (Slope) (mm)	0.283	0.392	0.109	27.7%	0.0063[b]
Observed Area					
Mean Change in GA Area (mm^2)	1.592	2.290	0.697	30.5%	0.0059[a]
Mean Rate of GA Growth (Slope) (mm^2)	1.221	1.889	0.668	35.4%	0.0050[b]

The estimates for the GATHER1 avacincaptad pegol 2 mg group vs. sham are from the MMRM model, drawing on all available data, including data from groups with different randomization ratios in Part 1 and Part 2 of the trial, and should not be interpreted as directly observed data.

GATHER2

MMRM Analysis	avacincaptad pegol 2 mg (N = 225)	Sham (N = 222)	Difference	% Difference	P-Value
Sq. Rt. Transformation					
Mean Change in GA Area (mm)	0.333	0.392	0.059	15.0%	0.0056[(b)]
Mean Rate of GA Growth (Slope) (mm)	0.336	0.392	0.056	14.3%	0.0064[(a)]
Observed Area					
Mean Change in GA Area (mm^2)	1.936	2.341	0.405	17.3%	0.0027[(b)]
Mean Rate of GA Growth (Slope) (mm^2)	1.745	2.121	0.376	17.7%	0.0039[(a)]

Explanatory notes - in the above presentation:

(a) Indicates pre-specified primary endpoint analysis; statistically significant;
(b) Indicates descriptive p-value.

As part of the pre-specified statistical analysis plan for GATHER2, we also analyzed the mean rate of growth (slope) in GA area for avacincaptad pegol 2 mg as compared to sham for pre-specified patient subgroups based on baseline lesion size, baseline visual acuity, baseline autofluorescence pattern, age, and gender. Avacincaptad pegol 2 mg showed a reduction in the mean rate of growth (slope) in GA area for all analyzed subgroups.

The pre-specified supportive endpoints in GATHER2 included the mean change in best corrected visual acuity, or BCVA, and the mean change in low luminance best corrected visual acuity, or LL BCVA, from baseline to month 12. For BCVA, a favorable trend for avacincaptad pegol 2 mg was observed, which is consistent with GATHER1. For LL BCVA, a favorable trend was not observed.

Trial Conduct and Patient Retention

We achieved a 12-month injection fidelity rate for GATHER2 of 92.5%. The 12-month injection fidelity rate for GATHER1 was 87%. The injection fidelity rate is calculated by dividing the total number of actual injections for all patients by the total number of expected injections based on the total number of patients enrolled in the trial. We believe injection fidelity to be the most important and stringent measure of patient retention because it reflects the timely administration of the study drug into the patient's eye.

The number of patients who withdrew or otherwise discontinued from the GATHER2 trial during the first 12 months was 25 (11.1%) in the avacincaptad pegol 2 mg group and 17 (7.7%) in the sham control group. We continue to focus on patient retention and closely monitor the COVID-19 pandemic and its effect on the trial.

Avacincaptad pegol Regulatory Pathway Following GATHER2

We believe that with the statistically significant results from our GATHER1 and GATHER2 trials and the safety profile of avacincaptad pegol to date, we have 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.

We recently submitted to the FDA the first part of our NDA, which includes the complete clinical data package for avacincaptad pegol, for rolling review of avacincaptad pegol, for the treatment of GA secondary to AMD. As previously disclosed, we received fast track designation from the FDA for avacincaptad pegol. One of the benefits of fast track designation is the potential for rolling review of an NDA. We requested rolling submission of our planned NDA, which the FDA granted. We plan to complete the submission of the NDA to the FDA for marketing approval of avacincaptad pegol for the treatment of GA secondary to AMD by the end of 2022.

We are also planning to submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, in 2023. Our plans are subject to feedback we may receive from planned interactions with regulatory authorities in Europe.

GATHER2 Open-Label Extension Study

We recently 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 have started patient enrollment 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.

Planned Development in Intermediate AMD

As previously disclosed, we were planning to initiate a clinical trial evaluating avacincaptad pegol for the treatment of intermediate AMD, subject to feedback from the FDA and other regulatory authorities. In September 2022, we obtained favorable feedback from the FDA on our development plans. We are continuing to engage with the FDA regarding our development plans and strategy for this important patient population.

STAR (STGD1 - Ongoing)

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. STAR, similar to GATHER1, was designed to be a Phase 2b screening trial, with the potential to demonstrate statistically significant results depending on the magnitude of the potential benefit observed. If the results are positive and statistically significant, we believe this trial could potentially serve as a clinical trial that can support an application for marketing approval. We initially enrolled 95 patients in the STAR trial, none of whom have any remaining study visits.

In July 2020, we reopened enrollment in this trial in the United States. We continue to enroll new patients and plan to enroll approximately 25 additional patients, with the goal of enrolling a total of approximately 120 patients. As we continue to enroll new patients, we continue to monitor the COVID-19 pandemic closely and may need to slow down or stop patient enrollment in certain geographies depending on the local situation. 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 Manufacturing

In early 2017, we completed the small scale manufacture of multiple batches of avacincaptad pegol drug substance that we are using to support clinical drug supply for the GATHER2 trial, the OLE study and the expanded STAR trial. 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. Recently, 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. 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 avacincaptad pegol drug substance at an adequate scale for potential commercial use. We experienced issues during technology transfer of the existing manufacturing process to this manufacturer, which resulted in delays to our timelines with this manufacturer. Subject to successful completion of scale up and validation activities, we currently plan to use Agilent as the primary source of supply of avacincaptad pegol drug substance upon launch, if approved, and the new manufacturer as a second source of supply of avacincaptad pegol drug substance. Validation requires that we demonstrate that the drug substance produced through the scaled up process can be produced consistently, delivering quality product meeting specifications. We are continuing analytical method development and qualification with our contract manufacturers and laboratories.

Starting in 2020, we have worked with a contract manufacturer to provide us with additional supply of avacincaptad pegol drug product to support our needs for the GATHER2 trial and the expanded STAR trial. We believe we have sufficient avacincaptad pegol drug product for these two clinical trials. In addition, we are working with our historical fill/finish manufacturer, Ajinomoto Bio-Pharma Services, or Ajinomoto, on fill/finish of avacincaptad pegol drug product with a new vial, which we believe will allow us to support a more efficient and robust fill/finish operation at a commercial scale. Ajinomoto has produced avacincaptad pegol drug product using the new vial, which we are using for a portion of the second-year study visits for patients in the GATHER2 trial and for the OLE study. We believe Ajinomoto has the capacity to supply us with avacincaptad pegol drug product with the new vial for our expected commercial supply needs upon launch, if approved.

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.

Avacincaptad Pegol Lifecycle Initiatives

We continue to pursue various lifecycle management initiatives for avacincaptad pegol. We have been exploring multiple sustained release delivery technologies for avacincaptad pegol, including analyzing and evaluating the resulting formulations of the technologies with avacincaptad pegol.

One of the technologies that we have evaluated is DelSiTech's proprietary silica-based sustained release technology. We have been encouraged by the results of preliminary feasibility studies of avacincaptad pegol formulated with DelSiTech's silica-based sustained release technology and as a result, in June 2022 we entered into a license agreement with DelSiTech, or the DelSiTech License Agreement, under which we obtained a worldwide, exclusive license under specified patent rights and know-how to develop and commercialize new formulations of avacincaptad pegol using DelSiTech's silica-based sustained release technology for treating diseases of the human eye. We plan to develop these sustained release delivery technologies for GA and earlier stages of AMD.

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.

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 selected IC-500 as the lead compound from our HtrA1 inhibitor program, which includes a number of small molecule compounds that show high affinity and specificity for HtrA1 when tested in vitro.

We plan to conduct additional preclinical studies to optimize the dosage, delivery and formulation of IC-500. As a result, we do not expect to submit an investigational new drug application for IC-500 mid-next year, as we had previously planned. We remain committed to this program.

Gene Therapy Research and Development Programs

IC-100: Product Candidate for RHO-adRP

We have been conducting the preclinical development of IC-100, our novel AAV gene therapy product candidate for the treatment of RHO-adRP. We have been considering our development options for this product candidate. We currently are seeking a collaborator or licensee for the future development and potential commercialization of IC-100.

IC-200: Product Candidate for BEST1-Related IRDs

We have been conducting the preclinical development of IC-200, our novel AAV gene therapy product candidate for the treatment of *BEST1*-related IRDs. We have been considering our development options for this product candidate. We currently are seeking a collaborator or licensee for the future development and potential commercialization of IC-200.

Minigene Programs

AAV vectors are generally limited as a delivery vehicle by the size of their genetic cargo, which is restricted to approximately 4,700 base pairs of genetic code. The use of minigenes seeks to deliver a smaller but still functional form of a larger gene packaged into a standard-size AAV delivery vector. The goal of minigene therapy is to deliver a gene expressing a protein that, although smaller than the naturally occurring protein, is nonetheless functional for purposes of treating the associated disease.

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. The sponsored research yielded a number of minigene constructs that show encouraging results when tested in a mouse model. 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. UMMS granted us an option to obtain an exclusive license to certain patent applications for this program. UMMS generated and evaluated several *ABCA4* minigene constructs in both *in vitro* and *in vivo* experiments, which yielded what we believe to be encouraging results. We are conducting additional experiments to optimize the constructs and assess their efficacy in the mouse model.

- **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 granted us an option to obtain an exclusive license to certain patent applications for this program. 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 have been delayed as a result of transitioning the work from UMMS to us.

Recent Impact of COVID-19

The COVID-19 pandemic and other macro-economic events, such as the military action taken by Russia against Ukraine, and governmental responses to those events have affected the world economy in various ways, including causing delays and challenges to the global supply chain and the work and operations of many manufacturers and service providers. We rely heavily on third-party contract manufacturing organizations, contract research organizations and other vendors to support our clinical trials, manufacturing activities and other business operations. We describe below some of the recent impacts of these macro-economic events on our business and operations.

Over the past two years, the pharmaceutical industry and the contract manufacturing organizations and suppliers supporting the industry as a whole have been impacted by the global supply chain disruptions in wake of the COVID-19 pandemic. For example, the new manufacturer we are working with as a second source of supply for avacincaptad pegol drug substance has experienced issues with procuring a number of raw materials due to supply chain interruptions, which caused several delays to our manufacturing timelines with this manufacturer. To date, we have not experienced any drug product supply issues impacting our GATHER2 and STAR clinical trials or the OLE study and we do not believe our overall timelines for avacincaptad pegol have been materially impacted as a result of supply chain issues affecting our contract manufacturers. The impact of the COVID-19 pandemic and future variants and subvariants on our operations remains uncertain and we are continuing to monitor the situation closely.

We do not believe that the COVID-19 pandemic, and our actions in response and the costs of those actions, have had a material impact on our financial position, results of operations, or cash flows for the three and nine months ended September 30, 2022. For further information on actual and potential impacts to us as a result of the COVID-19 pandemic, see the Risk Factors contained in this Quarterly Report on Form 10-Q.

Business Development and Financing Activities

As we continue the development of our product candidates and programs, prepare for the potential commercialization of avacincaptad pegol and evaluate our overall strategic priorities, we continue to pursue selective business development and financing opportunities that advance us toward our strategic goals. We have been focused on pursuing potential sustained release delivery technologies for avacincaptad pegol, such as DelSiTech's silica-based sustained release technology, for which we entered into the DelSiTech License Agreement. We plan to continue to evaluate, on a selective and targeted basis, additional opportunities to obtain rights to product candidates and technologies for retinal diseases, including additional sustained release delivery technologies for avacincaptad pegol that may be promising and meet our criteria. In addition, we continue to explore potential collaboration and out-licensing opportunities for the future development and potential commercialization of our product candidates, including potential collaboration opportunities for the future development and potential commercialization of avacincaptad pegol in one or more territories outside the United States and collaboration and out-license opportunities for the future development and potential commercialization of IC-100 and IC-200.

In July 2022, we executed a Loan and Security Agreement with Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or SVB, for a $250.0 million term loan facility, or the 2022 Term Loan Facility. The 2022 Term Loan Facility has tranched availability as follows:

- $50.0 million fully funded at closing.
- $50.0 million available at our option through December 15, 2022, subject to the GATHER2 trial achieving its protocol-specified primary endpoint and our having sufficient clinical data package to support the submission of an NDA to the FDA for avacincaptad pegol in GA.
- $25.0 million available at our option through September 30, 2023, subject to our submission of an NDA and its acceptance by the FDA for avacincaptad pegol before this date.
- $75.0 million available at our option through the earlier of (a) September 30, 2024 or (b) 90 days following FDA approval of the use of avacincaptad pegol for GA, subject to our achieving such approval; and
- $50.0 million available with lender approval.

Future capital draws are at our election and are in $5.0 million increments. The 2022 Term Loan Facility includes a 42 month interest only period and is extendable up to five years upon meeting certain conditions.

For information about our follow-on public offerings that we completed in July 2021 and October 2021 and more detailed information about the 2022 Term Loan Facility, please see the Liquidity and Capital Resources section of this Management's Discussion and Analysis of Financial Condition and Results of Operations. We expect to continue to pursue capital raising transactions when they are available on terms favorable to us and if the opportunity advances our strategic goals.

Financial Matters

As of September 30, 2022, we had cash, cash equivalents and available-for-sale securities of $320.5 million, inclusive of the $50 million we borrowed under the 2022 Term Loan Facility with Hercules and SVB in July 2022. We estimate our year-end 2022 cash, cash equivalents and available for sale securities to range between $265 and $275 million. 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 mid-2024. These estimates are based on our current business plan, including the continuation of our ongoing clinical development programs for ACP in GA secondary to AMD and STGD1, including the recently initiated OLE study, evaluating ACP for intermediate AMD, preparation and submission of an NDA and a MAA for ACP in GA, continuing preparations for potential commercialization of ACP for GA in the United States, pursuing DelSiTech's silica-based sustained release delivery technology and exploring additional sustained release delivery technologies for ACP, and the advancement of our IC-500 development program. These estimates do not include any potential new borrowings under the 2022 Term Loan Facility with Hercules and SVB, including the $50 million that we plan to borrow in the fourth quarter of 2022. Also excluded from these estimates are any potential approval or sales milestones payable to Archemix or any potential expenses for actual commercial launch of ACP, such as associated sales force expenses, any additional expenditures related to potentially studying ACP in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development we may pursue.

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. If our development efforts for any of our product candidates result in regulatory approval or if we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties.

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 academic research collaborators, contract research organizations, or CROs, 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 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 and nine months ended September 30, 2022 and September 30, 2021: For the nine months ended September 30, 2022, avacincaptad pegol research and development expenses include a $1.3 million upfront license fee related to lifecycle management programs that was previously allocated to other research and development costs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Avacincaptad Pegol	$ 14,974	$ 11,509	$ 53,040	$ 37,533
IC-500: HtrA1	694	348	2,013	1,320
IC-100: RHO-adRP	544	(272)	241	933
IC-200: BEST1	(384)	724	(344)	2,685
Other gene therapy	37	15	71	11
Prior product candidate Fovista	1	2	1	(7)
Personnel-related	6,162	4,277	17,578	13,247
Share-based compensation	2,681	1,476	8,108	4,138
Other	258	(144)	463	112
Total	$ 24,967	$ 17,935	$ 81,171	$ 59,972

As we continue our ongoing clinical trials and the OLE study, plan for and initiate clinical development of avacincaptad pegol in intermediate AMD 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 IC-500 to increase as we continue preclinical development. We expect our research and development expenses for IC-100 and IC-200 to be de minimis for the foreseeable near future. We expect our research and development expenses for our minigene research programs to remain largely unchanged as we continue those programs as currently planned. 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.

We expect the development of our product candidates will continue for at least the next several years. At this time, we cannot reasonably estimate that 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 avacincaptad pegol for indications outside of GA or for any of our other product candidates.

The successful development of our product candidates is subject to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and costs of our research and development activities, including manufacturing activities;
- the potential benefits of our product candidates over other therapies;
- preclinical development results and clinical trial results;
- the terms and timing of regulatory approvals;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates; and
- our ability to successfully file, prosecute, defend and enforce patent claims and other intellectual property rights, together with associated expenses.

A change in the outcome of any of these variables with respect to the development of our product candidates could mean a significant change in the costs and timing associated with the development of that product candidate. For example, we are conducting the GATHER2 trial, which is a Phase 3 clinical trial evaluating avacincaptad pegol for GA secondary to AMD, with the belief that data collected from this trial, together with other available data, are sufficient to support an application for marketing approval for this indication in the United States and the European Union. We may subsequently decide to, or be required by regulatory authorities to, conduct additional clinical trials for avacincaptad pegol in GA or conduct additional

nonclinical studies of avacincaptad pegol in order to seek or maintain regulatory approval or qualify for reimbursement approval. As a result of any of the above, we could be required to expend significant additional financial resources and time on the completion of development of avacincaptad pegol in GA. For example, based on our assessment of the data we have collected for avacincaptad pegol to date and the requirements of regulatory authorities, we are conducting a pharmacokinetic substudy involving a portion of the patients enrolled in the GATHER2 trial and an additional nonclinical study of avacincaptad pegol. In addition, we decided to conduct the OLE study. Each of the foregoing studies have resulted in increased research and development expenses for avacincaptad pegol.

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 to incur additional general and administrative expenses as we continue preparing for the potential commercialization of avacincaptad pegol.

Interest Income

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, which generate a nominal amount of interest income.

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 academic research collaborators, CROs, CDMOs and other vendors in connection with research and development and manufacturing activities.

We base our expenses related to academic research collaborators, 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 September 30, 2022 and 2021

	Three months ended September 30,		
	2022	2021	Increase (Decrease)
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 24,967	$ 17,935	$ 7,032
General and administrative	17,545	6,648	10,897
Total operating expenses	42,512	24,583	17,929
Loss from operations	(42,512)	(24,583)	17,929
Interest income, net	200	42	158
Other expense, net	(39)	(10)	29
Loss before income tax benefit	(42,351)	(24,551)	17,800
Income tax benefit	—	—	—
Net loss	$ (42,351)	$ (24,551)	$ 17,800

Research and Development Expenses

Our research and development expenses were $25.0 million for the three months ended September 30, 2022, an increase of $7.0 million compared to $17.9 million for the three months ended September 30, 2021. The increase in research and development expenses for the three months ended September 30, 2022 was primarily due to a $3.5 million increase in costs associated with avacincaptad pegol, including the ongoing GATHER2 trial and increased manufacturing activities. In addition, the increase in research and development expenses was due to a $3.1 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 $1.1 million decrease in costs associated with IC-200. The decreased costs for IC-200 primarily reflect decreased manufacturing and preclinical development activities.

General and Administrative Expenses

Our general and administrative expenses were $17.5 million for the three months ended September 30, 2022, an increase of $10.9 million compared to $6.6 million for the three months ended September 30, 2021. The increase in general and administration expenses for the three months ended September 30, 2022 was primarily due to increases in personnel costs, including share-based compensation associated with staffing for commercial preparation.

Interest Income, net

Interest income for the three months ended September 30, 2022 was $1.3 million compared to interest income of $42 thousand for the three months ended September 30, 2021. Interest income for the three months ended September 30, 2022 was partially offset by $1.1 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 September 30, 2021. The increase in interest income for the three months ended September 30, 2022 was primarily due to rising interest rates and an increase in our cash equivalents and marketable securities average balances.

Comparison of Nine Month Periods Ended September 30, 2022 and 2021

	Nine months ended September 30, 2020		
	2022	2021	Increase (Decrease)
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 81,171	$ 59,972	$ 21,199
General and administrative	45,764	21,688	24,076
Total operating expenses	126,935	81,660	45,275
Loss from operations	(126,935)	(81,660)	45,275
Interest income, net	815	184	631
Other expense, net	(30)	(13)	17
Loss before income tax benefit	(126,150)	(81,489)	44,661
Income tax benefit	—	—	—
Net loss	$ (126,150)	$ (81,489)	$ 44,661

Research and Development Expenses

Our research and development expenses were $81.2 million for the nine months ended September 30, 2022, an increase of $21.2 million compared to $60.0 million for the nine months ended September 30, 2021. The increase in research and development expenses for the nine months ended September 30, 2022 was primarily due to a $15.5 million increase in costs associated with avacincaptad pegol, including a $1.3 million upfront license fee related to lifecycle management programs for avacincaptad pegol, and a $8.3 million increase in personnel costs, including share-based compensation associated with additional research and development staffing. The increased costs for avacincaptad pegol were primarily due to the ongoing progress of the GATHER2 trial and increased manufacturing activities. The increase in research and development expenses was partially offset by a $0.7 million decrease in costs associated with IC-100 and a $3.0 million decrease in costs associated with IC-200. The decreased costs for IC-100 and IC-200 primarily reflect decreased manufacturing and preclinical development activities.

General and Administrative Expenses

Our general and administrative expenses were $45.8 million for the nine months ended September 30, 2022, an increase of $24.1 million compared to $21.7 million for the nine months ended September 30, 2021. The increase in general and administration expenses for the nine months ended September 30, 2022 was primarily due to increases in personnel costs, including share-based compensation associated with preparations for potential commercial launch of avacincaptad pegol in GA.

Interest Income, net

Interest income for the nine months ended September 30, 2022 was $1.9 million compared to interest income of $0.2 million for the nine months ended September 30, 2021. Interest income for the nine months ended September 30, 2022 was partially offset by $1.1 million of interest expense which was due to our borrowings under the 2022 Term Loan Facility. There was no interest expense for the nine months ended September 30, 2021. The increase in interest income for the nine months ended September 30, 2022 was primarily due to rising interest rates and an increase in our cash equivalents and marketable securities average balances.

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 the Novo Holdings A/S Agreement, 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 and October 2021 and borrowings under the 2022 Term Loan Facility with Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or 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 believe we have achieved the first milestone and can draw an additional $50.0 million at any time on or before December 15, 2022. We plan to borrow the full $50.0 million tranche that is available during the fourth quarter of 2022. An additional $50.0 million is available subject to the approval of the facility lenders' investment committees in their 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, was 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, was approximately $162.6 million.

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

Cash Flows

As of September 30, 2022, we had cash, cash equivalents and available for sale securities totaling $320.5 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 nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating Activities	$ (114,537)	$ (76,125)
Investing Activities	(48,410)	80,202
Financing Activities	54,600	109,429
Net change in cash and cash equivalents	$ (108,347)	$ 113,506

Cash Flows from Operating Activities

Net cash used in operating activities in the nine months ended September 30, 2022 and 2021 related primarily to net cash used to fund our avacincaptad pegol clinical trials and manufacturing activities, our preclinical development of IC-500, IC-100 and IC-200, 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 used in investing activities was $48.4 million for the nine months ended September 30, 2022, which related to the purchases of marketable securities. Net cash provided by investing activities was $80.2 million for the nine months ended September 30, 2021, which related to the maturities of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $54.6 million for the nine months ended September 30, 2022, which primarily consisted of $50.0 million of proceeds from the 2022 Term Loan Facility, partially offset by a $2.5 million payment for issuance costs, and $7.1 million of proceeds related to stock option exercises and purchases made under our employee stock purchase plan.

Net cash provided by financing activities was $109.4 million for the nine months ended September 30, 2021, primarily consisted of $107.8 million of net proceeds from our follow-on public offering in July 2021 and $1.7 million of proceeds related to stock option exercises and purchases made under our employee stock purchase plan.

Funding Requirements

Avacincaptad pegol is in clinical development, IC-500 is in preclinical development, and we are exploring multiple sustained release delivery technologies for avacincaptad pegol 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 avacincaptad pegol 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 avacincaptad pegol and any promising product candidates that emerge from our gene therapy research programs. We plan to find a collaborator or licensee for the future development and potential commercialization of IC-100 and IC-200; if we are not successful in finding a collaborator or licensee, we may need to continue the development of one or both of those product candidates by ourselves, which would increase our research and development expenses. 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 avacincaptad pegol. We are party to agreements with Archemix with respect to avacincaptad pegol, DelSiTech with respect to formulations of avacincaptad pegol with DelSiTech's silica-based sustained release delivery technology, the former equity holders of Inception 4 with respect to IC-500, the University of Florida Research Foundation, Incorporated, or UFRF, and Penn, with respect to IC-100 and IC-200, 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 avacincaptad pegol with DelSiTech's silica-based sustained release delivery technology, IC-100, IC-200 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:

- continue the development of avacincaptad pegol in GA and STGD1 and initiate development of avacincaptad pegol in intermediate AMD and potentially other indications;
- expand our outsourced manufacturing capabilities for avacincaptad pegol and IC-500 and establish commercial operations and sales, marketing and distribution capabilities for avacincaptad pegol;
- prepare an NDA and an MAA for avacincaptad pegol and seek marketing approval for any 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 avacincaptad pegol;
- 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 September 30, 2022, we had cash, cash equivalents and available-for-sale securities of $320.5 million, inclusive of the $50 million we borrowed under the 2022 Term Loan Facility with Hercules and SVB in July 2022. We estimate our year-end 2022 cash, cash equivalents and available for sale securities to range between $265 and $275 million. 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 mid-2024. These estimates are based on our current business plan, including the continuation of our ongoing clinical development programs for ACP in GA secondary to AMD and STGD1, including the recently initiated OLE study, evaluating ACP for intermediate AMD, preparation and submission of an NDA and a MAA for ACP in GA, continuing preparations for potential commercialization of ACP for GA in the United States, pursuing DelSiTech's silica-based sustained release delivery technology and exploring additional sustained release delivery technologies for ACP, and the advancement of our IC-500 development program. These estimates do not include any potential new borrowings under the 2022 Term Loan Facility with Hercules and SVB, including the $50 million that we plan to borrow in the fourth quarter of 2022. Also excluded from these estimates are any potential approval or sales milestones payable to Archemix or any potential expenses for actual commercial launch of ACP, such as associated sales force expenses, any additional expenditures related to potentially studying ACP in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development we may pursue.

We expect the development of our product candidates will continue for at least the next several years. Although we believe we have sufficient financial resources for the activities necessary to complete development of, including manufacturing scale-up and validation activities, and potentially seek marketing approval of avacincaptad pegol in GA, we expect we will require additional funding in order to launch and commercialize avacincaptad pegol in GA, if approved. We also expect we will require substantial, additional funding in order to complete the activities necessary to develop and commercialize avacincaptad pegol for other indications, a sustained release delivery technology for avacincaptad pegol 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 avacincaptad pegol for any other indication, a sustained release delivery technology for avacincaptad pegol 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 the planned submission and regulatory review of an NDA and an MAA for avacincaptad pegol in GA;
- the timing, scope and costs of establishing a commercial infrastructure for potential commercialization of avacincaptad pegol, 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 avacincaptad pegol and our other product candidates;
- the scope, progress, costs and results of our current and future avacincaptad pegol clinical programs and any further development we may undertake;
- our ability to establish collaborations on favorable terms, if at all, if we choose to do so, including a potential collaboration for the further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States;
- 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 avacincaptad pegol;
- 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 other preclinical development activities to enable us to submit an IND for this product candidate;
- 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.

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 avacincaptad pegol 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, or if we choose not to or are unable to find a collaborator for commercialization of avacincaptad pegol in one or more territories outside the United States. 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 avacincaptad pegol; 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 an application for marketing approval in the United States and the European Union. We may subsequently decide to, or be required by regulatory authorities to, conduct additional clinical trials or nonclinical studies of avacincaptad pegol in order to seek or maintain marketing approval or qualify for reimbursement approval. In addition, the COVID-19 pandemic may result in disruptions to the progress of the GATHER2 or STAR trials, 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 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 $162.6 million in net proceeds in an underwritten public offering of our common stock in October 2021, 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.

Until such time, if ever, when we can generate substantial product revenues, we may need or may seek to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. For example, in July 2022, we entered into the Loan Agreement with Hercules and SVB, providing for the 2022 Term Loan Facility, pursuant to which we have total borrowing capacity under several tranches of up to $250.0 million in aggregate principal amount, of which (i) $50.0 million has been drawn upon execution of the Loan Agreement, (ii) 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 or regulatory events for avacincaptad pegol as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Contractual Obligations and Commitments” and (iii) an additional $50.0 million is available subject to approval of the lenders’ investment committees in their discretion. However, if we do not satisfy the specified performance milestones or the lenders do not otherwise approve additional borrowings, we will not have access to the remaining amounts of the 2022 Term Loan Facility. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our existing stockholders' ownership interests would be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as common stockholders. The dilutive effect of future equity issuances may be substantial, depending on the price of our common stock at the time of such capital raise, with a lower stock price translating to greater dilution for existing stockholders. Debt financing and preferred equity financing, if available, would involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, making certain investments or entering into certain other transactions. For example, the covenants under the Loan Agreement include limitations on our ability to obtain additional financing, to make certain investments and to enter into certain other transactions. In addition, we have issued, and may in the future issue additional, equity securities as consideration for business development transactions, which may also dilute our existing stockholders' ownership interests.

If we raise additional funds through collaborations, royalty transactions, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Our need for additional financing may continue even if we are able to successfully develop one or more of our product candidates. Our future commercial revenues, if any, will be derived from sales of such product candidates, which may not be available for at least several years following completion of successful product development, if at all. In addition, if approved, our product candidates 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 in connection with a change in control or termination of employment by the employee for good reason or by us without cause, occur. For a description of these obligations, see our definitive proxy statement on Schedule 14A for our 2022 annual meeting of stockholders, as filed with the SEC on March 30, 2022.

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 and manufacturing activities. Expenditures to CROs and CDMOs represent significant costs in preclinical and clinical development. 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. 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.

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; (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 1 and plan to borrow the full $50.0 million tranche that is available during the fourth quarter of 2022. With the exception of the first $50.0 million tranche available on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at our election. 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. 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 fifty percent (50%) of the outstanding 2022 Term Loan Facility at such time or (y) maintain Qualified Cash in an amount greater than or equal to ninety percent (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 September 30, 2022, 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.

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 $320.5 million as of September 30, 2022, 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 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 September 30, 2022, 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 September 30, 2022. 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 September 30, 2022, 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 September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings

Descriptions of legal proceedings are set forth in "Note 8-Commitments and Contingencies" in the notes to the financial statements filed with this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. 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. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Business Plan, Financial Position and Need for Additional Capital

We are a development-stage company without any commercial products. The value of our company is highly dependent on the success and potential commercialization of avacincaptad pegol and our other research and development efforts and the amount of our available cash. Our research and development programs, which are focused on novel therapies and technologies, carry significant scientific and other risks. If any of these programs are not successful, the value of your investment may decline.

We are a development-stage company without any approved products. Our growth prospects and the future value of our company are dependent on the progress of our research and development programs, including our ongoing and any future clinical trials for avacincaptad pegol, our preclinical development program for IC-500, and our gene therapy research programs. In particular, we are highly dependent on the success of avacincaptad pegol, and any delays or issues with its potential marketing approval or its potential commercialization will likely cause the value of your investment to decline significantly. Drug development is a highly uncertain undertaking and carries significant scientific and other risks.

We may encounter unforeseen difficulties, complications, delays, expenses and other known and unknown factors. We may never be successful in developing or commercializing any of our product candidates or other programs. There is a high rate of failure in pharmaceutical research and development. Even if we have promising preclinical or clinical candidates, their development could fail at any time. Our failure could be due to unexpected scientific, safety or efficacy issues with our product candidates and other programs, invalid hypotheses regarding the molecular targets and mechanisms of action we choose to pursue or unexpected delays in our research and development programs resulting from applying the wrong criteria or experimental systems and procedures to our programs or lack of experience or other factors, including disruptions resulting from the COVID-19 pandemic and other macroeconomic factors, with the possible result that none of our product candidates or other programs result in the development of marketable products. Although we have results from two large-scale, pivotal clinical trials (GATHER1 and GATHER2) with safety and efficacy data that we believe are sufficient to seek marketing approval for avacincaptad pegol for GA, we need to complete activities necessary to apply for and obtain marketing approval, including the qualification of one or more commercial manufacturers through pre-approval inspections with regulatory authorities. We are working to transition from a company having a product development focus to a company capable of commercializing pharmaceutical products. At this time, we are continuing to hire commercialization personnel and build a commercial infrastructure for the potential commercialization of avacincaptad pegol, if approved. We may not be successful in such a transition, as our company has never conducted the sales, marketing, manufacturing and distribution activities necessary for successful product commercialization.

Because the value of our company is largely based on the prospects for our research and development programs and their potential to result in therapies capable of achieving marketing approval and generating future revenues, any failure, delay or setback for these programs will likely have a negative impact on the value of your investment. As we continue to invest in our research and development programs to generate data to support further development or applications to obtain marketing approval for commercialization, the amount of our available cash will continue to decline until we raise additional finances.

Companies in our industry face a wide range of challenging activities, each of which entails separate, and in many cases substantial, risk.

The long-term success of our company, and our ability to become profitable as a biopharmaceutical company, will require us to be successful in a range of challenging activities, including:

- designing, conducting and successfully completing preclinical research and development activities, including preclinical efficacy and IND-enabling studies, for our product candidates;
- making arrangements with third-party manufacturers and providers of starting materials for our product candidates, and having those manufacturers successfully develop manufacturing processes for drug substance and drug product and provide adequate amounts of drug product for preclinical and clinical activities in accordance with our expectations and regulatory requirements;
- designing, conducting and completing clinical trials for our product candidates;
- obtaining favorable results from required clinical trials, including for each ophthalmic product candidate, favorable results from two adequate and well-controlled pivotal clinical trials in the relevant indication;
- applying for and receiving marketing approvals from applicable regulatory authorities for the marketing and sale of our product candidates;
- making arrangements with third-party manufacturers for scale-up and commercial manufacturing, validating and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities and ensuring adequate supply of drug substance, drug product and starting materials used for the manufacture of drug substance and drug product;
- establishing sales, marketing and distribution capabilities, either internally or through collaborations or other arrangements, to effectively market and sell our product candidates, if and when approved;
- achieving acceptance of the product candidate, if and when approved, by patients, the medical community and third-party payors;
- if our product candidates are approved, obtaining from governmental and third-party payors adequate coverage and reimbursement for our product candidates and, to the extent applicable, associated injection procedures conducted by treating physicians;
- effectively competing with other therapies, including the existing standard of care, and other forms of drug delivery;
- maintaining a continued acceptable safety profile of the product candidate during development and following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, including under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, or FDCA, or the Orphan Drug Act if we choose to seek such protections for any of our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio; and
- complying with all applicable regulatory requirements, including Good Laboratory Practices, or GLP, Good Clinical Practices, or GCP, current Good Manufacturing Practices, or cGMP, and standards, rules and regulations governing promotional and other marketing activities.

Each of these activities has associated risks, many of which are detailed below and throughout this "Risk Factors" section. We may never succeed in these activities and, even if we do, may never generate revenues from product sales that are significant enough to achieve commercial success and profitability. Our failure to be commercially successful and profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decrease in the value of our company would also cause our stockholders to lose all or part of their investment.

We have a history of significant operating losses. We expect to continue to incur losses until such time, if ever, that we successfully commercialize one or more of our product candidates and may never achieve or maintain profitability.

Since inception, we have experienced significant cash outflows in funding our operations. To date, we have not generated any revenues from commercial product sales and 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 our prior Fovista licensing and commercialization agreement with Novartis Pharma AG, funds we received in connection with our acquisition of Inception 4 in October 2018, our follow-on public offerings, which we closed in February 2014, December 2019, June 2020, July 2021 and October 2021 and borrowings under the 2022 Term Loan Facility, pursuant to the Loan Agreement with Hercules and SVB. As of September 30, 2022, we had an accumulated deficit of $805.7 million. Our net loss was $42.2 million for the nine months ended September 30, 2022 and we expect to continue to incur significant operating losses for the foreseeable future.

Avacincaptad pegol is in clinical development, IC-500 is in preclinical development, and we are exploring multiple sustained release delivery technologies for avacincaptad pegol 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 avacincaptad pegol 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 avacincaptad pegol and any promising product candidates that emerge from our gene therapy research programs. We plan to find a collaborator or licensee for the future development and potential commercialization of IC-100 and IC-200; if we are not successful in finding a collaborator or licensee, we may need to continue the development of one or both of those product candidates by ourselves, which would increase our research and development expenses. 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 avacincaptad pegol. We are party to agreements with Archemix with respect to avacincaptad pegol, DelSiTech with respect to formulations of avacincaptad pegol with DelSiTech's silica-based sustained release delivery technology, the former equity holders of Inception 4 with respect to IC-500, the University of Florida Research Foundation, Incorporated, or UFRF, and Penn, with respect to IC-100 and IC-200, 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 avacincaptad pegol with DelSiTech's silica-based sustained release delivery technology, IC-100, IC-200 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:

- continue the development of avacincaptad pegol in GA and STGD1 and initiate development of avacincaptad pegol in intermediate AMD and potentially other indications;
- expand our outsourced manufacturing capabilities for avacincaptad pegol and IC-500 and establish commercial operations and sales, marketing and distribution capabilities for avacincaptad pegol;
- prepare an NDA and an MAA for avacincaptad pegol and seek marketing approval for any 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 avacincaptad pegol;
- 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.

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. See "—Risks Related to Product Development and Commercialization" for a further discussion of the risks we face in successfully developing and commercializing our product candidates and achieving profitability.

We expect we will require substantial, additional funding in order to complete the activities necessary to develop and commercialize avacincaptad pegol or any of our other product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate one or more of our product development programs or commercialization efforts. We may require additional funding beyond what we currently expect or sooner than we currently expect.

As of September 30, 2022, we had cash, cash equivalents and available-for-sale securities of $320.5 million, inclusive of the $50 million we borrowed under the 2022 Term Loan Facility with Hercules and SVB in July 2022. We estimate our year-end 2022 cash, cash equivalents and available for sale securities to range between $265 and $275 million. 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 mid-2024. These estimates are based on our current business plan, including the continuation of our ongoing clinical development programs for ACP in GA secondary to AMD and STGD1, including the recently initiated OLE study, evaluating ACP for intermediate AMD, preparation and submission of an NDA and a MAA for ACP in GA, continuing preparations for potential commercialization of ACP for GA in the United States, pursuing DelSiTech's silica-based sustained release delivery technology and exploring additional sustained release delivery technologies for ACP, and the advancement of our IC-500 development program. These estimates do not include any potential new borrowings under the 2022 Term Loan Facility with Hercules and SVB, including the $50 million that we plan to borrow in the fourth quarter of 2022. Also excluded from these estimates are any potential approval or sales milestones payable to Archemix or any potential expenses for actual commercial launch of ACP, such as associated sales force expenses, any additional expenditures related to potentially studying ACP in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development we may pursue.

We expect the development of our product candidates will continue for at least the next several years. Although we believe we have sufficient financial resources for the activities necessary to complete development of, including manufacturing scale-up and validation activities, and potentially seek marketing approval of avacincaptad pegol in GA, we expect we will require additional funding in order to launch and commercialize avacincaptad pegol in GA, if approved. We also expect we will require substantial, additional funding in order to complete the activities necessary to develop and commercialize avacincaptad pegol for other indications, a sustained release delivery technology for avacincaptad pegol 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 avacincaptad pegol for any other indication, a sustained release delivery technology for avacincaptad pegol 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 the planned submission and regulatory review of an NDA and an MAA for avacincaptad pegol in GA;
- the timing, scope and costs of establishing a commercial infrastructure for potential commercialization of avacincaptad pegol, 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 avacincaptad pegol and our other product candidates;
- the scope, progress, costs and results of our current and future avacincaptad pegol clinical programs and any further development we may undertake;

- our ability to establish collaborations on favorable terms, if at all, if we choose to do so, including a potential collaboration for the further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States;
- 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 avacincaptad pegol;
- 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 other preclinical development activities to enable us to submit an IND for this product candidate;
- 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 $162.6 million in net proceeds in an underwritten public offering of our common stock in October 2021, 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 avacincaptad pegol 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, or if we choose not to or are unable to find a collaborator for commercialization of avacincaptad pegol in one or more territories outside the United States. 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 avacincaptad pegol; 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 an application for marketing approval in the United States and the European Union. We may subsequently decide to, or be required by regulatory authorities to, conduct additional clinical trials or nonclinical studies of avacincaptad pegol in order to seek or maintain marketing approval or qualify for reimbursement

approval. In addition, the COVID-19 pandemic may result in disruptions to the progress of the GATHER2 or STAR trials, 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 develop one or more of our product candidates. Our future commercial revenues, if any, will be derived from sales of such product candidates, which may not be available for at least several years following completion of successful product development, if at all. In addition, if approved, our product candidates 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, when we can generate substantial product revenues, we may need or may seek to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. For example, in July 2022, we entered into the Loan Agreement with Hercules and SVB, providing for the 2022 Term Loan Facility, pursuant to which we have total borrowing capacity under several tranches of up to $250.0 million in aggregate principal amount, of which (i) $50.0 million has been drawn upon execution of the Loan Agreement, (ii) 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 or regulatory events for avacincaptad pegol as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Contractual Obligations and Commitments” and (iii) an additional $50.0 million is available subject to approval of the lenders’ investment committees in their discretion. However, if we do not satisfy the specified performance milestones or the lenders do not otherwise approve additional borrowings, we will not have access to the remaining amounts of the 2022 Term Loan Facility. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our existing stockholders' ownership interests would be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as common stockholders. The dilutive effect of future equity issuances may be substantial, depending on the price of our common stock at the time of such capital raise, with a lower stock price translating to greater dilution for existing stockholders. Debt financing and preferred equity financing, if available, would involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, making certain investments or entering into certain other transactions. For example, the covenants under the Loan Agreement include limitations on our ability to obtain additional financing, to make certain investments and to enter into certain other transactions.

In addition, we have issued, and may in the future issue additional, equity securities as consideration for business development transactions, which may also dilute our existing stockholders' ownership interests. For example, under the agreement and plan of merger pursuant to which we acquired IC-500, or the Inception 4 Merger Agreement, we issued an aggregate of 5,174,727 shares of our common stock as up-front consideration to the former equity holders of Inception 4. The Inception 4 Merger Agreement also requires us to make payments to the former equity holders of Inception 4 upon the achievement of certain clinical and regulatory milestones, subject to the terms and conditions set forth in the Inception 4 Merger Agreement. Those milestone payments will be in the form of shares of our common stock, calculated based on the price of our 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 under the Inception 4 Merger Agreement, 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 our common stock as of the close of business on the business day prior to the closing date of our acquisition of Inception 4, and will be payable in cash thereafter. In July 2019, we also issued 75,000 shares of our common stock to UMass as partial upfront consideration for the in-license of our miniCEP290 program, and are obligated to issue up to 75,000 additional shares to UMass upon the achievement of a development milestone.

In March 2021, we filed a shelf registration statement on Form S-3, or the March 2021 Shelf Registration, pursuant to which we may offer and sell shares of common stock, debt securities and other securities for aggregate gross sale proceeds of up to $300.0 million, of which we may offer and sell up to $100.0 million from time to time pursuant to an “at-the-market” sales agreement, or the ATM Agreement, we entered into in March 2021 with Cowen and Company, LLC, or Cowen, as agent, subject to the terms and conditions described in the ATM Agreement and SEC rules and regulations. In July 2021, we issued and sold 13,397,500 shares of our common stock in an underwritten public offering under the March 2021 Shelf Registration. We have not yet issued and sold any shares of common stock under our “at-the-market” offering program. In addition, in

October 2021, we filed an automatically effective shelf registration statement, or the October 2021 Shelf Registration, under which we may issue an indeterminate amount of shares of common stock, debt securities and other securities. In October 2021, we issued and sold 10,350,000 shares of our common stock in an underwritten public offering under the October 2021 Shelf Registration. If we make further sales under the March 2021 Shelf Registration or the October 2021 Shelf Registration or if we make sales under our "at-the-market" offering program, the sales could dilute our stockholders, reduce the trading price of our common stock or impede our ability to raise future capital.

If we raise additional funds through collaborations, royalty transactions, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our Loan Agreement with Hercules and SVB and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

As more fully described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments", in July 2022, we entered into the 2022 Term Loan Facility. The 2022 Term Loan Facility is secured by a lien on substantially all of our assets, including intellectual property, with certain limited exceptions set forth in the Loan Agreement. The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things, sell, transfer, lease or dispose of certain assets; incur indebtedness; encumber or permit liens on certain assets; make certain investments and acquisitions; make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common stock; and enter into certain transactions. Our business may be adversely affected by these restrictions on our ability to operate our business.

The covenants under the 2022 Term Loan Facility also include a requirement to maintain certain minimum levels of cash in accounts subject to a control agreement in favor of Hercules as agent, which we refer to as Qualified Cash.

Further, starting on August 15, 2024, we will be required to maintain a certain minimum amount of trailing six-month net product revenue from sales of avacincaptad pegol, tested on a quarterly basis. However, this revenue covenant will be waived during periods in 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 fifty percent (50%) of the outstanding term loan advances made under the 2022 Term Loan Facility at such time or (y) maintain Qualified Cash in an amount greater than or equal to ninety percent (90%) of the outstanding term loan advances made under the 2022 Term Loan Facility at such time.

A breach of any of the covenants under the Loan Agreement could result in a default under the 2022 Term Loan Facility. If an event of default under the 2022 Term Loan Facility occurs, including a material adverse effect, subject to certain exceptions, on our business, operations, properties, assets or financial condition, the Lenders could elect to declare all amounts outstanding, if any, to be immediately due and payable and terminate all commitments to extend further credit. If there are any amounts outstanding that we are unable to repay, the Lenders could proceed against the collateral granted to them to secure such indebtedness.

In addition, our outstanding debt combined with our other financial obligations and contractual commitments, could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash, cash equivalents and available for sale securities to the payment of interest on, and principal of, our debt, which would reduce the amounts available to fund working capital, commercialization expenditures, product development efforts and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash, cash equivalents and available for sale securities, potential future product revenues and funds from external sources. However, we may not have sufficient

funds or may be unable to arrange for additional financing to pay the amounts due under the 2022 Term Loan Facility. Funds from external sources may not be available on acceptable terms, if at all.

The COVID-19 pandemic, which is a fluid and evolving situation, has adversely affected and may continue to negatively affect our business and operations in a number of ways, and its long-term effects are uncertain. In addition, the pandemic and other macroeconomic events have caused substantial disruptions in the financial markets and economies, which could adversely affect our business and operations.

Beginning in March 2020, the COVID-19 pandemic and measures taken to contain it have affected our business and operations in a number of ways. These include, but are not limited to, the following:

- Clinical Trial Operations. In March 2020, we decided to delay the initiation of patient enrollment in our GATHER2 trial. As we initiated patient enrollment in June 2020, we and our clinical trial sites implemented new health and safety practices to mitigate the effects of the COVID-19 pandemic and to support patients and site staff. In addition, we added more than 30 new sites to the GATHER2 trial to help with patient recruitment. We may face difficulties in enrolling patients, retaining patients or maintaining scheduled visits to the extent patients are affected by the virus or lockdown measures or are fearful of visiting or traveling to our clinical trial sites because of the pandemic. We are aware that a number of patients initially enrolled in the STAR trial missed consecutive visits during the early months of the pandemic, and that a number of patients in our Latin America sites for GATHER2 missed visits because of the COVID-19 pandemic. We do not yet know whether the number of missed visits will increase or decrease in the GATHER2 or STAR trials, or what the impact of missed visits may be on patient retention in those trials or the trial results, especially because we are masked to the treatment of patients during the conduct of the trials. We do not know how the pandemic would affect the conduct of the OLE study. We have been and continue to monitor the situation closely. For a more detailed discussion of the impact of the COVID-19 pandemic on our clinical trial operations, please see the Risk Factor titled, "*The COVID-19 pandemic has affected and may continue to affect the initiation and conduct of our clinical trials, including the retention of patients for our GATHER2 clinical trial and patient recruitment and retention for our STAR clinical trial and the OLE study. It may have long-lasting effects on the conduct of clinical trials, which can make our ongoing and any future trials more difficult, costly or time consuming*."

- Third-Party Collaborators and Vendors. Many of our third-party contract manufacturers, academic research collaborators and contract research organizations limited their operations and staff during the COVID-19 pandemic, which resulted in delays to some of our manufacturing and research and development activities and limited our ability to be on site to oversee these activities. For example, the closure of animal research laboratories at UMMS for several months during 2020 caused delays to the progress of, and to our timelines for receipt of data from, our minigene research programs. Over the past two years, several of our vendors have been facing backlogs due to work and demands from other clients, including those who are developing vaccines or medicines for the COVID-19 pandemic, which has limited their availability to perform work for us. In addition, earlier this year, several of our vendors experienced high levels of absenteeism of their workforce due to the Omicron variant and as a result scaled back their operations. For example, many CROs have limited slots available for preclinical studies and experienced increased absenteeism of staff in wake of the Omicron variant; these factors caused a delay of our previously planned start date for our IND-enabling toxicology studies for IC-500. These operational and staffing limitations may cause further delays for our development and manufacturing activities. At this time, we do not know whether there will be further impact on the work of our third-party vendors and collaborators due to the COVID-19 pandemic.

- Supply Chain and Materials. Shortages, delays and governmental restrictions arising from the COVID-19 pandemic have disrupted and may continue to disrupt the ability of our contract manufacturers to procure items, such as raw materials, that are essential for the manufacture of our product candidates. For example, during 2020, our contract manufacturer for IC-500 drug substance experienced a shortage in obtaining one of the raw materials that was sourced from China, which was caused by the shutdown of local suppliers and the slowdown in trade due to the COVID-19 pandemic. This shortage delayed our process development activities for the drug substance for IC-500 by a number of months. In addition, since 2020, there have been shortages of various animals used in research studies, such as several types of non-human primates, which are typically sourced from China, due to the COVID-19 pandemic and disruptions to the global supply chain. Although our development programs have not yet been affected by these shortages, we are continuing to monitor the situation. Furthermore, the new manufacturer we are working with as a second source of supply for avacincaptad pegol drug substance has experienced issues with procuring a number of raw materials due to supply chain interruptions, which caused several delays to our manufacturing timelines with this manufacturer. To date, we have not experienced any drug product supply issues impacting our GATHER2 and STAR clinical trials or the OLE study and we do not believe our overall timelines for avacincaptad pegol have been materially impacted as a result of supply chain issues affecting our contract manufacturers. We continue to monitor our supply chain closely.

- Remote Working. We instituted company-wide remote working starting in March 2020. Starting in 2021, our employees began returning to our offices on a voluntary basis in compliance with new health and safety policies we implemented. We expect to operate under a hybrid (partially remote and partially in office) working model for the foreseeable future.

The progression of the COVID-19 pandemic remains fluid and its impact on our business and operations remains uncertain. Throughout the course of the pandemic thus far, many countries and regions, including many states in the United States, have experienced surges in the number of new cases, including as a result of new variants to the SARS-COV-2 virus, which have caused public health authorities to reimpose restrictive measures. In addition, although the FDA has approved (or provided emergency use authorization for) a number of vaccines as well as vaccine booster shots, there continue to be challenges with increasing the percentage of vaccinated individuals among the general population, and the long-term safety and efficacy and ability of these vaccines to slow transmission, including against new variants and subvariants of the virus, are largely unknown. In the United States and some other countries, vaccine mandates remain controversial and the reluctance of many individuals to get COVID-19 vaccines may affect the work of our vendors and other third parties providing services for us. As a result, governments may continue to deploy measures to contain the pandemic for a prolonged period of time.

In addition, many companies have been using force majeure clauses in their contracts to excuse or delay performing under their contracts, including as a result of supply chain interruptions. Our contract manufacturers, contract research organizations and other third parties on whom we rely for goods or services may make similar claims. If any such force majeure claims were successful, then not only would our timelines be delayed but also our right to recover for any economic damages due to the delay would be limited. Because we rely on many single-source suppliers, any such claims from them are likely to result in a delay to our timelines or otherwise adversely affect our operations or financial position.

The full extent to which the COVID-19 pandemic and other macroeconomic events will directly or indirectly impact our business, results of operations and financial condition will depend on developments that are uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and new variants and subvariants of the virus, the actions taken to contain it or lessen its impact, and the economic impact on local, regional, national and international markets. We may experience additional disruptions to our clinical trials or supply chains, and reduced operations at third-party facilities, such as our clinical trial sites and suppliers, and delays in interactions with regulatory agencies or obtaining approvals for our product candidates. Additional public health crises and natural disasters, such as future epidemics or pandemics or those resulting from the effects of climate change, may arise in the future. Any of these events may materially and adversely affect our business operations and financial condition.

Our strategy of obtaining additional rights to products, product candidates or technologies for the treatment of retinal diseases may not be successful. Although we entered into a license agreement with DelSiTech for its sustained release delivery technology, that technology may not be successful and/or we may not be successful in obtaining rights to and developing other sustained release delivery technologies for avacincaptad pegol. We may not be successful in finding a collaborator or licensee for IC-100 and/or IC-200.

An element of our strategy over the past few years has been to expand our pipeline through in-licensing or acquiring the rights to products, product candidates or technologies that would complement our strategic goals as well as other compelling retina opportunities. Since early 2018, we have completed multiple acquisition, in-license, exclusive option and sponsored research arrangements for product candidates and other technologies intended to treat retinal diseases. For example, in June 2022, we entered into a license agreement, or the DelSiTech License Agreement, with DelSiTech Ltd., or DelSiTech, pursuant to which we obtained a worldwide, exclusive license under specified patent rights and know-how to develop and commercialize new formulations of avacincaptad pegol using DelSiTech's silica-based sustained release technology for treating diseases of the human eye. We plan to continue to evaluate additional opportunities to in-license or acquire products, product candidates and technologies on a selective and targeted basis, with a focus on potential additional sustained release delivery technologies for avacincaptad pegol that are promising and meet our criteria. We may also continue to consider other alternatives, including mergers, acquisitions, asset purchases or sales and/or other transactions involving our company as a whole or other collaboration transactions, including potential collaboration opportunities for further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States and collaboration or out-license opportunities for further development and potential commercialization of IC-100 and/or IC-200. Our business development efforts may fail to result in our acquiring rights to additional products, product candidates or technologies, or may result in our consummating transactions with which you do not agree.

We may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties for several reasons. The success of this strategy depends partly upon our ability to identify, select and acquire or in-license promising product candidates and technologies. For potential sustained release delivery technologies, that process typically involves conducting a feasibility study of avacincaptad pegol formulated with the sustained release delivery technology and analyzing the resulting formulation, which can be time-consuming, costly and uncertain in outcome. If a

formulation is promising based on the analytical results, we could then proceed to negotiate a longer term collaboration. For example, we in-licensed DelSiTech's silica-based sustained release delivery technology after reviewing feasibility results that we believe are promising; however, further testing and studies may undermine our belief. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or technology is lengthy and complex. With respect to potential product candidates or technologies for which we have entered into option agreements, our agreements generally do not have fixed economic or other key terms for definitive agreements, and we may not obtain favorable terms if and when we choose to exercise our option to acquire or in-license any product candidates or technologies.

The in-licensing and acquisition of pharmaceutical products is an area characterized by intense competition, and a number of companies (both more established and early stage biotechnology companies) are also pursuing strategies to in-license or acquire product candidates or technologies that we may consider attractive. More established companies may have a competitive advantage over us due to their size, cash resources and greater research, preclinical or clinical development, manufacturing or commercialization capabilities, while earlier stage companies may be more aggressive or have a higher risk tolerance. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Other sustained release delivery technology companies that we are working with may be less willing to enter into long-term license or collaborations with us in light of our DelSiTech license. We also may be unable to in-license or acquire the rights to the relevant product candidate or technology on terms that would allow us to make an appropriate return on our investment. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts or we may incorrectly judge the value of an acquired or in-licensed product candidate or technology.

Further, any product candidate that we acquire or in-license would most likely require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. For potential sustained release delivery technologies with avacincaptad pegol, we expect any promising technologies, including our in-licensed DelSiTech's silica-based sustained release delivery technology, would require extensive preclinical and clinical testing and investment in manufacturing before any potential approval by the FDA or other regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate would not be shown to be sufficiently safe and effective for approval by regulatory authorities.

If we are unable to successfully obtain rights to suitable product candidates or technologies, our business, financial condition and prospects for growth could suffer. In addition, acquisitions and in-licensing arrangements for product candidates and technologies are inherently risky, and ultimately, if we do not complete an announced acquisition or license transaction or integrate an acquired or licensed product candidate or technology successfully and in a timely manner, we may not realize the benefits of the acquisition or license to the extent anticipated and the perception of the effectiveness of our management team and our company may suffer in the marketplace. In addition, even if we are able to successfully identify, negotiate and execute one or more transactions to acquire or in-license new product candidates or technologies, our expenses and short-term costs may increase materially and adversely affect our liquidity.

In addition, acquisitions and in-licenses may entail numerous operational, financial, regulatory and legal risks, including:

- exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions or in-licensing transactions;
- inability to receive regulatory clearance from government agencies, such as the Federal Trade Commission, to close transactions after announcement;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to maintain uniform standards, controls, procedures and policies;
- restructuring charges related to eliminating redundancies or disposing of assets as part of any such combination;

- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset;
- increased amortization expenses or, in the event that we write-down the value of acquired assets, impairment losses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- inability to retain personnel, key customers, distributors, vendors and other business collaborators integral to an in-licensed or acquired product candidate or technology;
- potential failure of the due diligence process to identify significant problems, liabilities or other shortcomings or challenges of an acquired or licensed product candidate or technology, including problems, liabilities or other shortcomings or challenges with respect to intellectual property, data or product quality, revenue recognition or other accounting practices, partner disputes or issues and other legal and financial contingencies and known and unknown liabilities; and
- entry into therapeutic approaches, indications or markets in which we have no or limited direct prior development or commercial experience and where competitors in such markets have stronger market positions.

Risks Related to Regulatory Approval of Our Products

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue would be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, recordkeeping, labeling, storage, advertising, promotion, sale and distribution and import and export, are subject to comprehensive regulation by the FDA, the EMA and comparable regulatory agencies in other countries.

In general, the FDA and similar regulatory authorities outside the United States require two adequate and well-controlled clinical trials demonstrating safety and effectiveness for marketing approval for an ophthalmic pharmaceutical product. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and rely in part upon third-party CROs to assist us in this process. Securing marketing approval requires obtaining positive safety and efficacy data from required clinical trials, as well as the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the product's manufacturing processes to, and inspection of manufacturing facilities by, the relevant regulatory authorities. The FDA or other regulatory authorities may determine that a product candidate that we may develop is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

The FDA issued guidance in March 2022 stating that it would treat co-packaged ophthalmic products, which generally consist of a drug component that provides the primary active pharmaceutical ingredient along with device components such as needles or syringes, as a combination product. We expect that our planned finished form of avacincaptad pegol drug product will be treated by the FDA as a combination product. We do not believe that this guidance has affected our strategy and timelines for submitting an NDA to the FDA for avacincaptad pegol for the treatment of GA secondary to AMD.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and information concerning similar product candidates as our product candidates. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other

studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Marketing approval of novel product candidates, for example aptamers such as avacincaptad pegol, manufactured using specialized manufacturing processes, can be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to regulatory agencies' lack of experience with them. We believe that the FDA has only granted marketing approval for one aptamer product to date.

Accordingly, if we or our collaborators experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for such product candidate may be harmed and our ability to generate revenues would be materially impaired.

Our intended regulatory pathway for obtaining marketing approval for avacincaptad pegol for GA is subject to several assumptions, including that we will be able to rely on the results from our GATHER1 and GATHER2 trials. Although we received a written agreement from the FDA under a SPA for the overall design of GATHER2 and the FDA indicated that as part of a future NDA submission, it will consider the GATHER1 data using the original prespecified primary efficacy endpoint analysis, together with the new FDA preferred method that we are using for GATHER2, the FDA, the EMA or other regulatory authorities may not accept the design or results of the GATHER1 or GATHER2 trials. To date, we have not had any formal interactions with the EMA regarding the GATHER1 or GATHER2 results. We may decide to or may be required to enroll additional patients, collect additional safety data or conduct additional clinical trials or nonclinical studies to seek or obtain approval for avacincaptad pegol in GA.

Based on the statistically significant results from our GATHER1 and GATHER2 trials and the safety profile of avacincaptad pegol to date, we believe we have 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. This belief is based on the assumption that a reduction in mean rate of GA growth over 12 months, measured by FAF based on readings at three time points: baseline, month 6 and month 12, is a primary endpoint of clinical relevance. The FDA, the EMA or other regulatory authorities may not agree with our view that the observed reduction in the rate of GA growth is clinically relevant or meaningful, or may require us to correlate this reduction in rate of GA growth with another outcome more directly associated with visual function. We understand that many regulatory authorities outside the United States, including those in Europe, may require a sponsor to show a functional benefit to vision for marketing approval in GA. If we are required to show a functional benefit to vision to obtain marketing approval, we may need to conduct additional clinical trials, which may not ultimately demonstrate a functional benefit to vision to the satisfaction of these regulatory authorities. Since receiving the 12-month results from the GATHER1 trial, we have not had any interactions with the EMA regarding the GATHER1 data or the design of or results from GATHER2. The FDA, the EMA or other regulatory authorities may also disagree with our conclusion regarding the robustness of the data from the GATHER1 and GATHER2 trials and may conduct their own sensitivity analyses yielding different results. Even if we meet with the FDA, EMA or other regulatory authorities, we likely will not have an opportunity to obtain definitive confirmation from the FDA, EMA or other regulatory authorities regarding the sufficiency or robustness of the data from our clinical trials, including the GATHER1 and GATHER2 trials, until such time as we submit an application for marketing approval and receive a response from the applicable authority. If the GATHER1 and GATHER2 trial results are not considered robust, or if regulatory authorities do not accept the study designs of GATHER1 or GATHER2, then in order to seek marketing approval we may need to conduct, in addition to the GATHER2 trial, one or more clinical trials that meet the applicable regulatory requirements in order to obtain marketing approval.

In parallel discussions with those for the GATHER2 SPA, the FDA indicated that, as part of a future NDA for avacincaptad pegol, it would consider the results from GATHER1 using the original prespecified primary efficacy endpoint analysis, together with a post-hoc analysis we performed using the FDA-preferred method we are using for the GATHER2 trial (mean rate of growth (slope) estimated based on GA area measured by FAF in the relevant timepoints). Although we believe that the post-hoc analyses from the GATHER1 trial are consistent with the positive results from the original prespecified analysis from the trial, any analyses, whether prespecified or post-hoc, that are intended to support an application for marketing approval are a matter of review for the FDA and other regulatory authorities, who may disagree with our methodologies and analyses for any number of reasons.

Based on discussions with the FDA, following the GATHER1 trial, we believe we need to conduct one additional clinical trial with enough patients such that we will have safety data for a minimum of 300 patients having received the dose of avacincaptad pegol for which we are seeking approval, or a higher avacincaptad pegol dose, independent of indication, for a minimum of 12 months, with 24-month safety data available for some portion, but not all, of these 300 patients. We designed our GATHER2 trial to meet these requirements. We believe that we would be able to rely on safety data from our GATHER1

and GATHER2 trials in GA secondary to AMD, including the 24-month data that we will be collecting from GATHER2, as well as our STAR trial evaluating avacincaptad pegol for STGD1, to support our planned applications for marketing approval of avacincaptad pegol in GA in the United States and the European Union. However, since receiving the 12-month results from the GATHER1 trial, we have not had any scientific advice or other formal interactions with the EMA or competent national authorities in the European Union or United Kingdom regarding the sufficiency of the GATHER1 and GATHER2 trials, including our primary efficacy endpoints and analyses, to support an application for marketing approval. As we continue to engage with regulatory authorities, including in Europe, we may receive feedback that is not consistent with our expectations, including potential disagreements by the EMA and other regulatory authorities with what we understand are the requirements of the FDA. Regulatory authorities may require us to enroll additional patients, collect additional safety data, conduct additional trials or take other actions, which would require us to revise our development plans for avacincaptad pegol, which could potentially increase the costs of our avacincaptad pegol clinical programs and delay our expected timelines. For example, based on our assessment of the data we have collected for avacincaptad pegol to date and the requirements of regulatory authorities, we are conducting a pharmacokinetic substudy involving a portion of the patients enrolled in the GATHER2 trial and an additional nonclinical study of avacincaptad pegol. Any delays or unfavorable results from those studies may impact our timelines for seeking and potentially obtaining approval for avacincaptad pegol in GA. In addition, because of the COVID-19 pandemic or other reasons, we may experience a higher than anticipated rate of dropouts and missed visits and treatments in our GATHER2 and STAR trials, which could result in our not having adequate safety data for a sufficient number of patients to obtain marketing approval in GA.

Furthermore, although we have not observed any adverse events or serious adverse events attributable by the investigators to the drug product in our GATHER1 or GATHER2 trials, they may manifest as we continue to conduct our GATHER2 trial, in our STAR trial or in any other subsequent clinical trials we or a potential collaborator may undertake for avacincaptad pegol. When we follow patients for a longer period of time or collect safety data from a greater number of patients, such as with the recently initiated OLE study, we may observe safety events that we have not previously observed. For a further discussion of the safety risks in our trials, see the risk factor herein entitled "*If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of such product candidates. There are a number of known safety risks associated with our product candidates and currently unknown safety issues may arise during development.*"

Our ongoing clinical trials and any future clinical trials or other studies for avacincaptad pegol that we or a potential collaborator may undertake may yield inconsistent safety or efficacy results with those we have observed to date or otherwise fail to demonstrate sufficient safety or efficacy to justify further development or to ultimately seek or obtain marketing approval. Any negative results from our ongoing or any future clinical trials or other studies for avacincaptad pegol will likely adversely affect our business and the value of your investment in our company.

Although we have obtained agreement with the FDA on a SPA for GATHER2, a SPA does not guarantee marketing approval of, or any other particular outcome from, regulatory review.

In July 2021, the FDA agreed to a SPA for GATHER2. Under the SPA procedure, 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 an NDA. A SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of the overall protocol design for a clinical trial intended to support a future marketing application, but it does not indicate FDA concurrence on every protocol detail. A SPA agreement also does not ensure the receipt of marketing approval or that the approval process will be faster than conventional procedures. A determination regarding marketing approval is addressed during the review of a submitted NDA and depends on efficacy and safety results and an evaluation of the overall benefits and risks of treatment after review of the data from the development program in its totality.

Even after the FDA agrees to the design, execution, and analysis proposed in a protocol reviewed under the SPA process, the FDA may revoke or alter its agreement if a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun. A SPA agreement may also be changed through written agreement between the sponsor and the FDA. A revocation or alteration in our existing SPA could delay or prevent approval of our planned NDA for avacincaptad pegol. In addition, any significant change to the protocol for a clinical trial subject to a SPA would require prior FDA approval, which could delay implementation of such a change and the conduct of the related clinical trial. The FDA retains significant discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in such jurisdictions. The approval requirements in foreign jurisdictions may differ significantly from those in the United States.

In order to market and sell our product candidates in the European Union and many other jurisdictions, we or our third-party commercialization partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional nonclinical or clinical testing. For example, although we have obtained a SPA from the FDA for the GATHER2 trial, the EMA or other regulatory authorities may not agree with the overall protocol design for the GATHER2 trial, or may require us to conduct additional clinical trials or non-clinical studies. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our third-party commercialization partners may not obtain marketing and/or reimbursement approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We and our third-party commercialization partners may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If our third-party commercial partners fail to obtain marketing approval in certain jurisdictions, it may diminish the value of our product candidate to them and cause them to terminate their relationship with us.

In June 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the European Union, commonly referred to as “Brexit”. Following protracted negotiations, the UK left the European Union on January 31, 2020 and European Union rules and regulations ceased to apply to the UK starting on January 1, 2021. The Medicines and Healthcare products Regulatory Agency, or the MHRA, is now the sole decision maker for marketing authorizations of pharmaceutical products in the UK, except for Northern Ireland. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the UK the body of European Union law governing medicinal products that pre-existed before the UK’s withdrawal from the European Union. In December 2020, the UK government and the European Union agreed on a long-term trade agreement to govern economic relations going forward. Since the existing regulatory framework for pharmaceutical products in the UK is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime for pharmaceutical products in the UK. As a result of Brexit, we expect we will need to submit a separate application to the MHRA for marketing approval in the UK, in addition to the planned MAA for the EMA. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

A fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program or for other reasons.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and if the product demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product’s application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA’s time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process or for other reasons.

In April 2020, the FDA granted fast track designation to avacincaptad pegol for the treatment of GA secondary to dry AMD. Even though avacincaptad pegol has received fast track designation, we must continue to follow the requirements of the program in order to maintain the fast track designation, and even if we maintain the designation, we may not ultimately experience a faster development process, review or approval compared to conventional FDA procedures. The FDA's grant of fast track designation to avacincaptad pegol for the treatment of GA secondary to dry AMD does not imply that the FDA will grant fast track designation to avacincaptad pegol for another indication, or that the FDA will grant fast track designation for any of our other product candidates, if we choose to apply for fast track designation.

A breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates would receive marketing approval.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to help design the clinical trials in an efficient manner.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead decide not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not ensure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or that the time period for FDA review or approval will not be shortened.

We currently do not have orphan drug designations or orphan drug exclusivity for any product candidate. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same or similar drug and treat the same indications as our product candidates, we may not be able to have our product candidates approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union and that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

If we request orphan drug designation for any of our product candidates in one or more indications, there can be no assurances that the FDA or the European Commission will grant any of our product candidates such designation. Additionally, the designation of any of our product candidates as an orphan product does not guarantee that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission, as the case may be, during that marketing exclusivity period from approving another marketing application for a product that constitutes the same or similar drug treating the same indication, except in limited circumstances. If another sponsor receives such approval before we do, regardless of our orphan drug designation, we may be precluded from receiving marketing approval for our product candidate during the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the European Union. The exclusivity period in the United States can be extended by six months if the sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. In the European Union, the exclusivity period can be extended by two years following the completion of an agreed pediatric investigation plan. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked, or a competing sponsor may be allowed on the market, if any regulatory agency

determines that the request for designation was materially defective or if the sponsor having orphan drug exclusivity is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because a competing sponsor's drug could nevertheless be approved for the same condition if certain requirements are met. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the later drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued guidance stating that it would consider two gene therapy products to be different products if they express different transgenes or use different vectors. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior by making a major contribution to patient care;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of the orphan medicinal product.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business.

If the FDA, EMA or other foreign regulatory authorities approve generic versions of any of our product candidates that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our products are approved, even if we still have patent protection for such products. Competition that our products could face from generic versions of our products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those products.

Risks Related to Manufacturing

We do not have any internal manufacturing capabilities and use third parties to manufacture our product candidates on a contract or purchase order basis. We may encounter manufacturing issues that could cause delays in our development programs or increase costs. We may experience delays in regulatory approval of our product candidates if we or our contract manufacturers do not satisfy applicable regulatory requirements. If any of our product candidates is approved, a manufacturing issue could result in product shortages, which could impair our ability to commercialize our products and generate revenue.

We do not have internal manufacturing facilities and use or plan to use outside contract manufacturers to manufacture avacincaptad pegol, IC-500 and any other product candidates that we may acquire or in-license. The manufacturing processes for our product candidates are technically complex. Problems with developing, executing or scaling up the manufacturing process could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or delays to our programs. We may encounter problems achieving adequate quantities and quality of clinical-grade or commercial-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

We may encounter problems hiring and retaining scientific, manufacturing and quality assurance and control personnel needed to oversee our contract manufacturers, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. As our contract manufacturers scale up manufacturing of any product candidate, we may encounter unexpected issues relating to the manufacturing processes or the quality, purity or stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues, or may need to use alternative manufacturers. Resolving these issues could result in significant delays and may result in significantly increased costs. If we underestimate the demand for an approved product or the timing for the need for that product, given the long lead times required to manufacture or obtain regulatory approvals for our products and/or manufacturing facilities, we could potentially face commercial drug product supply shortages. If we experience significant delays or other obstacles in producing any approved product at commercial scale, our ability to market and sell any approved products may be adversely affected and our business could suffer.

The manufacturing processes and the facilities of our third-party manufacturers are subject to inspection and approval by the FDA and other regulatory authorities, referred to as a pre-approval inspection, before we can commence the commercial sale of any approved product candidate, and thereafter on an ongoing basis. None of our third-party manufacturers have undergone a pre-approval inspection by the FDA for avacincaptad pegol or any of our other product candidates. Failure by us or our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in delays in the approval of our applications for marketing approval, as well as regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. If any of our third-party manufacturers are found to have delayed, denied, limited or refused a drug inspection, our drug substance or drug product could be deemed adulterated. Based on the severity of the regulatory action, our clinical or commercial supply of drug substance or drug product could be interrupted or limited, which could have a material adverse effect on our business.

Any problems in our manufacturing process or our third-party contract manufacturers' facilities could make us a less attractive collaborator for potential collaborations, including with larger pharmaceutical companies. Problems in our manufacturing process or facilities also could restrict our ability to meet market demand for our products.

For a further discussion of the risks associated with our reliance on third-party manufacturers, including the effects of the COVID-19 pandemic on our third-party manufacturers, see the risk factor herein entitled, "*We contract with third parties for the manufacture of and for providing starting materials for our product candidates for preclinical development activities and clinical trials and expect to continue to do so in the future, including to support potential commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or product candidates of sufficient quality, which could delay, prevent or impair our development or commercialization efforts. The COVID-19 pandemic has affected our contract manufacturers' operations and the manufacture of our product candidates.*"

As we plan for the potential commercialization of avacincaptad pegol, we and our third-party manufacturers will need to complete several activities to ensure the continued supply of drug substance and drug product for ongoing and future clinical trials we conduct for avacincaptad pegol and to support potential future commercial supply of avacincaptad pegol. Any delay or failure in completing these activities could cause delays in the development of avacincaptad pegol or its potential approval or could result in inadequate clinical or commercial product supply.

In order to obtain and maintain regulatory approval for avacincaptad pegol, our third-party manufacturers will be required to produce avacincaptad pegol drug substance with consistent quality and to execute fill/finish services on a repeated basis and document their ability to do so. In order for us to successfully commercialize avacincaptad pegol, if approved, our manufacturers also need to be able to produce quantities at a commercial scale. If our third-party manufacturers are unable to satisfy these requirements, our business would be materially and adversely affected.

In early 2017, we completed the small scale manufacture of multiple batches of avacincaptad pegol drug substance that we are using to support clinical drug supply for the GATHER2 trial, the OLE study and the expanded STAR trial. Although we

believe we have adequate avacincaptad pegol drug substance for the GATHER2 trial, the OLE study and the expanded STAR trial, this supply may not be sufficient for our needs over the duration of the trials or for any additional trials we may conduct. 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. Recently, 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. We are continuing to work with Agilent on additional scale up and validation activities. Agilent may not be successful in validating the manufacturing process for producing avacincaptad pegol drug substance at a larger scale.

In parallel, we are working with a new contract manufacturer with the goal of assessing whether this manufacturer can produce avacincaptad pegol drug substance at an adequate scale for potential commercial use. We experienced issues during technology transfer of the existing manufacturing process to this manufacturer, which resulted in delays to our timelines with this manufacturer. Subject to successful completion of scale up and validation activities, we currently plan to use Agilent as the primary source of supply of avacincaptad pegol drug substance upon launch, if approved, and the new manufacturer as a second source of supply of avacincaptad pegol drug substance. Validation requires that we demonstrate that the drug substance produced through the scaled up process can be produced consistently, delivering quality product meeting specifications.

Starting in 2020, we have worked with a contract manufacturer to provide us with additional supply of avacincaptad pegol drug product to support our needs for the GATHER2 trial and the expanded STAR trial. We believe we have sufficient avacincaptad pegol drug product for these two clinical trials. In addition, we are working with our historical fill/finish manufacturer, Ajinomoto Bio-Pharma Services, or Ajinomoto, on fill/finish of avacincaptad pegol drug product with a new vial, which we believe will allow us to support a more efficient and robust fill/finish operation at a commercial scale. Ajinomoto has produced avacincaptad pegol drug product using the new vial, which we are using for a portion of the second-year study visits for patients in the GATHER2 trial and for the OLE study. We believe Ajinomoto has the capacity to supply us with avacincaptad pegol drug product with the new vial for our expected commercial supply needs upon launch, if approved. If Ajinomoto is unable to provide us and/or a potential collaborator with avacincaptad pegol drug product for potential commercial use, we will need to use alternative suppliers, which may increase our costs and delay our timelines.

In order to obtain regulatory approval for avacincaptad pegol, we expect we will need to demonstrate that the drug substance produced through the scaled up process, together with the finished drug product in the container closure system to be used commercially, are comparable to the drug substance and drug product we are currently using in our clinical trials. Under applicable regulatory guidance, comparability can be established through a combination of analytical, nonclinical or clinical data. Our plan to demonstrate comparability is subject to review by the FDA and other health authorities. Based on feedback from the FDA, we are using avacincaptad pegol drug product in the new vial for a portion of the second-year study visits for patients in the GATHER2 trial, which adds potential variability to the trial. If we are unable to sufficiently demonstrate comparability to the FDA or other health authorities, or if the FDA or other health authorities require analytical, nonclinical or clinical comparability data beyond what our plans currently provide for, our timelines to complete the development of and seek regulatory approval for avacincaptad pegol could be impacted.

We order the 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. However, we may not be able to agree to terms or may need to agree to unfavorable terms in order to secure adequate supply. We believe this supplier has the capacity to supply the PEG at the scale that we will need for commercial manufacturing. If this supplier is unable to supply us the PEG in line with our expectations, we believe there are a limited number of alternative suppliers for this important starting material, and if we need to use those suppliers, it could increase our costs and delay our manufacturing plans for avacincaptad pegol.

Each of these activities is costly, time-consuming and uncertain in outcome. We may not be able to successfully validate the scaled up process for manufacturing avacincaptad pegol drug substance, or we may need to manufacture at a larger scale for our future commercial needs, demonstrate comparability of avacincaptad pegol drug substance manufactured through the scaled up process or comparability of the drug product in the container closure system to be used commercially, in each case, with the avacincaptad pegol previously used in our clinical trials, or establish the long-term stability of the avacincaptad pegol drug product stored in the new vial container. The new manufacturers we have engaged or may engage in the future have not had previous experience with avacincaptad pegol and there may be additional issues with technology transfer. We may need to perform additional work beyond what we currently plan to establish manufacturing and analytical capabilities sufficient to obtain regulatory approval of our manufacturing process for avacincaptad pegol and to support potential commercial operations. In addition, we may not be able to secure adequate supply of avacincaptad pegol drug substance, including the PEG starting material used to make avacincaptad pegol drug substance, and avacincaptad pegol drug product for our future needs, including

to support potential commercial launch, and we may need to secure alternative contract manufacturers or suppliers sooner than we currently expect. If any of the foregoing events occur, it could result in delays or increased costs to support our future development and commercialization of avacincaptad pegol.

Some of the standards of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which establishes basic guidelines and standards for drug development in the United States, the European Union, Japan and certain other countries, do not apply to oligonucleotides, including aptamers. As a result, there are limited established generally accepted manufacturing or quality standards for the production of oligonucleotides such as avacincaptad pegol.

We are continuing to establish manufacturing capabilities for IC-500. We plan to conduct additional formulation optimization activities.

We are working with a number of CDMOs to conduct scale up and cGMP manufacturing of the drug substance for IC-500 for early-stage clinical trials. We are working with a CDMO to conduct cGMP manufacturing and fill/finish of the drug product for IC-500 for our planned GLP toxicology studies and early-stage clinical trials. Our contract manufacturers have developed a manufacturing process for IC-500 drug substance and a formulated drug product. We are planning additional preclinical studies to optimize the dosage, delivery and formulation. Manufacturing, including process development, formulation development, drug substance and drug product manufacturing, can be costly and time-consuming. If we are unable to successfully manufacture and formulate IC-500 in line with our expectations, we may switch to a backup HtrA1 inhibitor or cease developing our HtrA1 inhibitor program altogether.

The manufacture of gene therapy products is complex with a number of scientific and technical risks, some of which are common to the manufacture of drugs and biologics and others of which are unique to the manufacture of gene therapies.

Gene therapy drug products are complex and difficult to manufacture. We believe that the high demand for clinical gene therapy material and a scarcity of potential contract manufacturers may cause long lead times for establishing manufacturing capabilities for gene therapy drug development activities. Even after a manufacturer is engaged, any problems that arise during manufacturing, including during process development and cGMP manufacturing, may result in unanticipated delays to our timelines, including delays attributable to securing additional manufacturing time slots. In 2020, we experienced several delays to our cGMP manufacturing activities for IC-100 and IC-200 because of a number of manufacturing issues at our CDMO. There may also be long lead times to manufacture or procure starting materials such as cell banks or plasmids. In particular, plasmids and other starting materials for gene therapy manufacture are usually sole sourced, as there are a limited number of qualified suppliers. The progress of our gene therapy programs is highly dependent on these suppliers providing us or our contract manufacturers with the necessary starting materials that meet our requirements in a timely manner. As previously disclosed, due to an issue with one of the starting materials used for our manufacturing process for IC-100, we had to delay our cGMP manufacturing run at our CDMO and reschedule the run for a later date based on the CDMO’s availability. A failure to procure or a shortage of necessary starting materials likely would delay our manufacturing and development timelines.

A number of factors common to the manufacturing of biologics and drugs could also cause production or quality issues for gene therapies, including raw material or starting material variability in terms of quality, consistency in cell growth, productivity or cell line stability issues, product and process impurities, material shortages of any kind, shipping, distribution, storage and supply chain failures, cell culture contamination, equipment malfunctions, operator errors, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, epidemics and pandemics, or acts of god that are beyond our or our contract manufacturer's control. It is often the case that early stage process development is conducted with materials that are not manufactured using cGMP starting materials, techniques or processes and which are not subject to the same level of analysis that would be required for clinical grade material. We may encounter difficulties in translating the manufacturing processes used to produce research grade materials to cGMP compliant processes, and any changes in the manufacturing process may affect the safety and efficacy profile of our product candidates. Although we were successful in releasing cGMP batches of IC-100 and IC-200 produced by our CDMO, we have not yet conducted any manufacturing activities, including process development, for any of our minigene research programs.

An important part of manufacturing drug products is performing analytical testing. Analytical testing of gene therapies involves tests that are more complex in scope and take a longer time to develop and to conduct as compared to those used for traditional drugs. We, our contract manufacturers and our contract research organizations need to spend considerable time and resources to develop assays and other analytical tests for our gene therapy product candidates, including assays to assess the potency of our gene therapy product candidates. Some assays need to be outsourced to specialized testing laboratories. Even when assays are developed, they need to be further tested, qualified and validated, which may take substantial time and resources. Because of the lagging nature of analytical testing, we may proceed with additional manufacturing and other

development activities without having first fully characterized or released our manufactured materials. If the results of the testing fail to meet our expectations or applicable requirements, we may need to delay or repeat certain manufacturing and development activities.

Risks Related to Product Commercialization

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidates and other programs from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies, as well as generic and biosimilar companies, worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. We also will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future.

Our business strategy is focused on developing transformative therapies for retinal diseases, including GA, intermediate AMD and a number of orphan inherited retinal diseases. There are multiple companies pursuing the development of therapeutics targeting the complement pathway for age-related retinal diseases. Some of them have better name recognition, more resources and a longer history of developing therapies than we do. Competition in this field is intense and especially for many inherited retinal diseases, there is a limited number of potential patients. If any of our competitors obtains FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, our competitors could establish a strong market position before we are able to enter the relevant market, which may significantly limit the commercial opportunity for our product candidates.

Our commercial opportunity could also be reduced or eliminated if one or more of our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient to use or are less expensive than our product candidates. For example, the method of administration of avacincaptad pegol, intravitreal injection, is commonly used to administer ophthalmic drugs for the treatment of severe diseases and is generally accepted by patients facing the prospect of severe visual loss or blindness. A therapy that offers a less invasive or less frequent method of administration, however, might have a competitive advantage over one administered by monthly intravitreal injections, depending on the relative safety of the other method of administration. Our competitors may also be pursuing similar lifecycle management programs, such as sustained release delivery technologies. Furthermore, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of less expensive or more convenient products.

Many of our competitors have significantly greater financial and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our timelines may be delayed to the extent clinical trials conducted by our competitors are enrolling patients that would otherwise be eligible to participate in our trials at the same time we are seeking to enroll these patients.

Based on publicly available information, we are aware of the following research and development programs that may be competitive with programs we are pursuing. Other competitive programs may exist of which we are not aware.

Competitive considerations for GA or dry AMD:

- We are aware that LumiThera, Inc. has a medical device using its LT-300 light delivery system, which is approved in the European Union for the treatment of dry AMD. In addition, there are a number of products in preclinical and clinical development by third parties to treat GA or dry AMD. In general, these product candidates can be categorized based on their proposed mechanisms of action. The mechanisms of action for these product candidates include complement system and inflammation suppression, visual cycle modulators, antioxidants and neuroprotectants, cell and gene therapies and vascular perfusion enhancers. We are aware that AstraZeneca PLC (which acquired Alexion

Pharmaceuticals, Inc. in 2021), Akari Therapeutics, Plc, Annexon Inc., Apellis Pharmaceuticals, Inc., or Apellis, Applied Genetic Technologies Corporation, or AGTC, Biogen Inc., Gemini Therapeutics, Inc. (which merged with Disc Medicine, Inc.), Gyroscope Therapeutics (which was recently acquired by Novartis AG), IONIS Pharmaceuticals, Inc. (in collaboration with Roche AG), Janssen Pharmaceuticals Inc. (which acquired its program through the acquisition of Hemera Biosciences, LLC), Kanaph Therapeutics Inc, NGM Biopharmaceuticals Inc. and Novartis AG each have complement inhibitors in development for GA or dry AMD, including, in the cases Gyroscope Therapeutics and Janssen Pharmaceuticals, complement inhibitor gene therapies and AGTC and Gemini Therapeutics each has a research program on complement factor H gene therapy. We believe that the most advanced of these programs is Apellis's pegylated, synthetic peptide targeting complement protein C3, for which Apellis announced topline 12-month data from two Phase 3 clinical trials in September 2021, and Apellis submitted an application for marketing approval with the FDA in June 2022 and plans to submit a major amendment to that application in November 2022, with an expected updated Prescription Drug User Fee Act, or PDUFA, date in February 2023. Apellis could obtain marketing approval for its product candidate in advance of when we might reasonably expect to obtain marketing approval for avacincaptad pegol in GA or IC-500 in GA, if at all. Moreover, we are aware that several other companies, including Allegro Ophthalmics, LLC, Alkeus Pharmaceuticals Inc., Astellas Pharma Inc., Aviceda Therapeutics, Boehringer Ingelheim, Lineage Cell Therapeutics, Inc. (which was acquired by Roche AG), Ocugen, Inc., ONL Therapeutics, Inc., Regenerative Patch Technologies, Roche AG, Stealth BioTherapeutics Corp. and Visus Therapeutics, are pursuing development programs for the treatment GA or dry AMD using different mechanisms of action outside of the complement system, including Genentech, Inc. (an affiliate of Roche AG) and Gemini Therapeutics, which are pursuing HtrA1 inhibition as a mechanism of action. We believe that the most advanced HtrA1 inhibitor program in development was Genentech's monoclonal antibody HtrA1 inhibitor, which was being studied in a Phase 2 clinical trial until it was discontinued in October 2022.

Competitive considerations for Stargardt disease:

- There are a number of products in preclinical research and clinical development by third parties to treat Stargardt disease. We are aware that AGTC, Alkeus Pharmaceuticals, Inc., Beam Therapeutics Inc., Biogen, Generation Bio Co., Kubota Vision Inc. (formerly Acucela), Lin BioScience, Inc., ProQR Therapeutics N.V., or ProQR, and Spark Therapeutics (a subsidiary of Roche AG) each have research or development programs in Stargardt disease. Three of these programs, Alkeus, Kubota and Lin BioScience, are exploring the use of oral therapeutics, while AGTC, Nightstar and Spark are each using a gene therapy approach, Beam is using a base editing approach, and ProQR is using an RNA-based approach. Kubota’s product candidate, to which the FDA and the EMA granted orphan drug designation in August 2020, is in Phase 3 development while Alkeus’s product candidate is in Phase 2 development. In addition, several academic organizations have early stage programs in Stargardt disease.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing avacincaptad pegol or any of our other product candidates, if and when any such product candidate is approved. We may encounter difficulties hiring and effectively deploying a sales force.

As a company, we have no experience in the sale, marketing or distribution of pharmaceutical products. Starting in 2021, we began hiring commercialization personnel and are in the process of hiring additional commercialization personnel, including field-based sales personnel, and planning and setting up a sales, marketing and distribution infrastructure. To achieve commercial success for any approved product, we must either develop a sales, marketing and distribution organization or outsource those functions to third parties. We expect that our commercial strategy for any of our product candidates, including whether to retain commercial rights and market and sell the product candidate ourselves or to utilize collaboration, distribution or other marketing arrangements with third parties, would be determined based on a variety of factors, including the size and nature of the patient population, the disease area, the particular indications for which the product is approved, the territories in which the product may be marketed and the commercial potential for such product candidate. In addition, our commercial strategy would vary depending on whether the disease is typically treated by general ophthalmology practitioners or specialists, such as retinal specialists, and the likely degree of acceptance of our product candidate by the relevant physicians in various markets. At this time, we are planning to sell, market and distribute avacincaptad pegol, if approved for GA, in the United States ourselves.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a qualified sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed

or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to adequate numbers of physicians who may prescribe our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

There are also risks involved with having third parties perform sales, marketing and distribution services on our behalf. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute ourselves any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not or are unable to establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we would not be successful in commercializing our product candidates, if approved.

Even if any of our product candidates receives marketing approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for any of our product candidates may be smaller than we estimate.

The degree of market acceptance of any product candidate that we are developing or we may develop, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments, including the existing standard of care;
- any restrictions in the label on the use of our products in combination with other medications or with certain devices;
- any restrictions in the label on the use of our products to or by a subgroup of patients;
- for treatment regimens calling for multiple intravitreal injections on the same day, restrictions in the label imposing a waiting period between intravitreal injections;
- our and any commercialization partner’s ability to offer our products at competitive prices;
- availability and timeliness of governmental and third-party payor coverage and adequate reimbursement;
- increasing reimbursement pressures on treating physicians due to the formation of accountable care organizations and the shift away from traditional fee-for-service reimbursement models to reimbursement based on quality of care and patient outcomes;
- willingness of the target patient population and physicians to try new therapies, particularly in light of the existing available standard of care or to the extent our product candidates require invasive procedures for administration;
- prevalence and severity of any side effects or perceived safety concerns, such as CNV; and
- whether competing products or other alternatives are more convenient or easier to administer, including alternatives that offer a less frequent dosing regimen than monthly intravitreal injections, in the case of avacincaptad pegol, come to market.

Our development program for avacincaptad pegol in GA uses anatomical primary endpoints, the mean rate of change in GA growth over 12 months, in the case of GATHER1, and the mean rate of growth (slope) estimated based on GA area over 12 months, in the case of GATHER2. We believe that this efficacy assessment is most likely to demonstrate clinical relevance for an investigational product across a heterogeneous GA patient population and other potential assessments, such as comparisons

of visual acuity, are not as clinically meaningful for patients with GA. However, to date there is no direct functional corollary to the anatomical measures that we are using as our primary endpoints for GATHER1 and GATHER2. Although we evaluated visual acuity as a secondary endpoint in the GATHER1 trial, the trial was not designed to reliably assess differences in mean changes in visual acuity with statistical significance. Patients, physicians and payors may not recognize the value of, and we may not be able to obtain marketing or reimbursement approval for, avacincaptad pegol without demonstrating a functional benefit to vision. To do so, we may need to conduct additional clinical trials or sub-studies, which may not ultimately demonstrate a functional benefit to vision.

In addition, the potential market opportunity for any product candidate is difficult to estimate precisely. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our expectations of the safety and effectiveness of the relevant product candidate, the expected patient population for our product candidates, our industry knowledge, the competitive landscape for the indications for which we are developing our product candidates, market response to anti-VEGF agents currently approved for treatment of wet AMD, third-party research reports and other surveys. The potential market opportunity for our product candidates may also differ across geographies. While we believe that our internal assumptions are reasonable, any of these assumptions could prove to be inaccurate, and the actual market for such product candidates could be smaller than our estimates of our potential market opportunity.

There is a variety of factors that could contribute to the actual number of patients who receive an approved therapy being less than our estimates of the potential addressable market. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, patients may not be amenable to treatment with our products or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, the severity of the progression of a disease up to the time of treatment, especially in certain degenerative conditions such as GA, likely will diminish the therapeutic benefit conferred by a new drug product due to irreversible cell death. For example, certain GA patients may have experienced the loss of certain portions of retinal tissue that disproportionately affected their functional vision, and these patients may not value a treatment that can only slow the growth of additional GA lesions without providing a treatment to their loss of functional vision. On the other hand, patients with intermediate AMD are often asymptomatic as to loss of vision; therefore they may not seek or value having a treatment for their condition, especially a treatment involving monthly injections, which is the current dosing regimen for avacincaptad pegol. In addition, physicians, including retina specialists and general ophthalmologists, and their patients may not be aware of the risks of disease progression or of the availability of treatments, once approved. If the number of patients that may benefit from the treatments we are seeking to develop is lower than we expect, our business, financial condition, results of operations and prospects may be adversely affected.

Even if we are able to commercialize any of the product candidates that we may develop, the product may become subject to unfavorable pricing regulations, pricing dynamics, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Health care reform, including increasing scrutiny of drug prices, is an issue of intense political focus, particularly in the United States. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals or in ways that could alter the mechanism by which pharmaceutical prices are negotiated or otherwise determined. Many countries outside the United States require approval of the sale price of a drug before it can be marketed, and to apply for and obtain such an approval in certain countries, we or a commercialization partner may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control or negotiation even after initial approval is granted. In particular for avacincaptad pegol in GA and for many countries in Europe, we may need to demonstrate a relative benefit in functional vision in order to obtain reimbursement approval, although our clinical trials, which use an anatomic endpoint as the primary efficacy endpoint, are not designed to demonstrate a functional benefit with statistical significance. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our or any commercialization partner's commercial launch of the product, possibly for lengthy time periods, which would negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval and are widely accepted and prescribed or used by physicians.

In addition, even in countries where pharmaceuticals are not subject to strict pricing regulations through a governmental review and approval process, we may nonetheless face an unfavorable pricing environment as a result of political pressure or market dynamics. The perceived high cost for pharmaceutical products to treat orphan diseases, where manufacturers seek to recoup development costs and earn a profit for a therapy intended to treat a relatively small patient population, may attract increased political and public scrutiny, as seen recently with a number of gene therapies that entered the market. Moreover, if we obtain marketing approval for a product candidate, such as avacincaptad pegol, in more than one indication, including, for example in an orphan indication such as STGD1 and a non-orphan indication such as GA, such a product candidate likely would only be sold at one price in any given country, regardless of the indications for which it is prescribed. This dynamic may result in our charging a price that does not generate profits in each indication for which the product is approved.

Our ability and the ability of any commercialization partner to commercialize a product candidate successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A major trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors, particularly Medicare, have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications and encouraging the substitution of lower cost or generic products. Pricing pressures experienced by the pharmaceutical industry may be further exacerbated by legislative and policy changes under consideration by the Biden Administration, the U.S. Congress and many states. See later in the Risk Factors section for a discussion of the expected impact of the recently passed Inflation Reduction Act. We expect that avacincaptad pegol, if approved for GA, would be reimbursed in large part by Medicare Part B and therefore, these cost containment measures will likely affect our pricing and reimbursement strategies.

Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician, which are generally covered by the "buy and bill" reimbursement model under Medicare Part B. We may choose to, or be required by market dynamics to, implement access and reimbursement policies that may not be successful in driving use of and reimbursement for our products, if approved. We or any commercialization partner may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies that may be on the market. If coverage and adequate reimbursement are not available or reimbursement is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution costs. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States, which many members of the U.S. Congress expressed an interest in pursuing. In September 2020, HHS issued a rule permitting limited importation of drugs from Canada. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our and any commercialization partner’s inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our financial condition, or our ability to raise capital needed to commercialize products.

Product liability lawsuits against us or any future commercialization partner could divert resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop or in-license.

We face an inherent risk of product liability exposure related to the testing of any product candidate that we develop in human clinical trials, and we and any future commercialization partner will face an even greater risk if we commercially sell any products that we develop or in-license. If we become subject to or otherwise cannot successfully defend ourselves against claims that our product candidates or our products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop or in-license;
- withdrawal of clinical trial participants;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop or in-license.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin commercializing an approved product. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, including coverage for any local jurisdictions where we conduct clinical trials. In addition, if a commercialization partner were to become subject to product liability claims or were unable to successfully defend themselves against such claims, any such commercialization partners could be more likely to terminate such relationship with us and therefore substantially limit the commercial potential of our products.

Risks Related to Product Development

Drug development is a highly uncertain undertaking. Our research and development efforts may not be successful or may be delayed for any number of reasons, in which case potential clinical development, marketing approval or commercialization of our product candidates could be prevented or delayed.

Before obtaining approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Prior to initiating clinical trials, we must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well as IND-enabling toxicology studies. Drug research, including the gene therapy research we are pursuing, may never yield a product candidate for preclinical or clinical development. Early stage and later stage research experiments and preclinical studies, including the feasibility studies and analytical testing we are performing for potential sustained release delivery technologies for avacincaptad pegol and the preclinical studies we are conducting and planning to conduct for IC-500, may fail at any point or produce unacceptable or inconclusive results for any number of reasons, and even if completed, may be time-consuming and expensive. As a result of these risks, a potentially promising product candidate may never be tested in humans. For example, we observed different findings across the two different species in which we tested IC-100 in preclinical toxicology studies, which caused us to evaluate our development options for this product candidate. At this time, we plan to seek a collaborator or licensee for the further development of this product candidate.

Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, our pivotal Phase 3 Fovista program for the treatment of wet AMD failed to produce positive safety and efficacy data that support the use of Fovista in wet AMD, despite the results from preclinical testing and earlier clinical trials of Fovista, including a large Phase 2b trial with a statistically significant efficacy signal. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. These risks include, but are not limited to, the following:

- we may not be able to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials for any preclinical product candidates that we are developing;

- we or our contract manufacturers may be unable to develop a viable manufacturing process for any product candidates that we are developing;
- the supply or quality of our product candidates or other materials necessary to conduct preclinical development and clinical trials of our product candidates may be insufficient or we may face delays in the manufacture and supply of our product candidates for any number of reasons, including as a result of interruptions in our supply chain, including in relation to the procurement or quality of starting materials, such as the polyethylene glycol, or PEG, used for the manufacture of avacincaptad pegol, and issues with the packaging, distribution, storage and import/export of materials and products;
- we or our contract research organizations may be unable to complete necessary analytical method development or qualification for testing our product candidates;
- we may not be able to successfully scale up or validate a manufacturing process for one or more of our product candidates, including the manufacturing process for avacincaptad pegol, and may need to rely on second source suppliers for adequate supply of drug substance and/or drug product in line with our needs and expectations;
- regulators or institutional review boards may not agree with our clinical trial designs, including our selection of endpoints, or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations or clinical trial sites, especially in cases where we are working with contract research organizations or clinical trial sites we have not worked with previously;
- our contract research organizations, clinical trial sites, contract manufacturers, providers of starting materials and packagers and analytical testing service providers may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we, through our clinical trial sites, may not be able to locate and enroll a sufficient number of eligible patients to participate in our clinical trials as required by the FDA or similar regulatory authorities outside the United States, especially in clinical trials for orphan or other rare diseases;
- we, through our clinical trial sites, may not be able to maintain enrolled patients for scheduled visits and treatments, or to retain patients altogether, especially in light of the COVID-19 pandemic, which could result in missing data from our clinical trials, potentially leading to uninterpretable results or a clinical trial not being sufficiently powered to demonstrate an efficacy benefit;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements, including GCPs, or a finding that the participants are being exposed to unacceptable health risks;
- as there are no therapies approved for GA, intermediate AMD, or Stargardt disease, in either the United States or the European Union, the regulatory pathway for product candidates in those indications, including the selection of efficacy endpoints and their clinical meaningfulness, is subject to review and acceptance by various regulatory authorities;
- there may be changes in regulatory requirements and guidance or we may have changes in trial design that require amending or submitting new clinical trial protocols;
- there may be changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies beyond those we currently contemplate or to abandon product development programs;
- the number of patients required for clinical trials of our product candidates to demonstrate statistically significant results may be larger than we anticipate. This risk may be heightened for clinical trials in orphan diseases, for which the natural history of the disease is less understood, making it more difficult to predict the drug effect

required to adequately demonstrate efficacy, and because there are fewer affected individuals available to participate in clinical trials; and

- the cost of clinical trials of our product candidates, including the costs of manufacturing activities to support those clinical trials, may be greater than we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we contemplate, if we otherwise change our clinical development plans, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use limitations, distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Despite our ongoing efforts, we may not complete any of our ongoing or planned development activities for our product candidates. The timing of the completion of, and the availability of results from, development activities is difficult to predict. For clinical trials in particular, we do not know whether they will begin as planned, will need to be restructured or will be completed on schedule, or at all. The progress of our clinical trials may be dependent on macro-economic events beyond our control, such as the COVID-19 pandemic. For example, the pandemic and governmental measures instituted in response to the pandemic have caused a number of missed visits in the GATHER2 trial and may cause additional patients to miss visits or drop out of the trial, which could result in missing data from this trial. Furthermore, our development plans may change based on feedback we may receive from regulatory authorities throughout the development process or for other reasons. For example, we believe that with the statistically significant results from our GATHER1 and GATHER2 trials and the safety profile of avacincaptad pegol to date, we have 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. Our expectations regarding the requirements to demonstrate the safety and efficacy of avacincaptad pegol for GA may change as we continue to have interactions with the FDA and potentially with the EMA and other regulatory authorities, and as new regulatory or third party information, including information from one of our competitors who is seeking marketing approval from the FDA for its complement inhibitor for GA, becomes available. If we experience delays in manufacturing, testing or marketing approvals, our product development costs would increase. Significant product development delays also could allow our competitors to bring products to market before we do, could impair our ability to successfully commercialize our product candidates, including by shortening any periods during which we may have the exclusive right to commercialize our product candidates, and may otherwise harm our business and results of operations.

Our development of avacincaptad pegol is based on a novel mechanism of action that is unproven in GA, intermediate AMD and STGD1 and poses a number of scientific and other risks, and we may not be successful in developing avacincaptad pegol in the indications we are pursuing or in any other indication we may choose to pursue.

We are currently targeting GA and intermediate AMD, which are an advanced form and an earlier form of AMD, respectively, and STGD1 with avacincaptad pegol. The causes of AMD are not completely understood. In addition to advanced age, there are environmental and genetic risk factors that contribute to the development of AMD including ocular pigmentation, dietary factors, a positive family history for AMD, high blood pressure and smoking. Although we believe there is a scientific rationale for pursuing the development of inhibitors of the complement system as potential pharmaceutical treatments for GA, and that the results from our GATHER1 and GATHER2 trials of avacincaptad pegol in GA secondary to AMD and from a competitor's trials of its complement inhibitor in GA support our view, this approach may not prove successful for treating GA. Similarly, although there is nonclinical scientific literature supporting the potential use of complement system inhibitors for the treatment of STGD1, we have not yet completed a clinical trial assessing avacincaptad pegol for the treatment of STGD1 and

do not have any unmasked data regarding the efficacy of avacincaptad pegol in this indication. As a result, this approach may not prove successful.

Avacincaptad pegol is designed to inhibit complement protein C5. There are no FDA or EMA approved products that utilize C5 inhibition as a mechanism of action to treat GA, intermediate AMD or STGD1. There have been other investigational products using complement inhibition as a mechanism of action for the treatment of GA, including inhibition of C5, that ultimately proved to be unsuccessful.

Our plans to pursue avacincaptad pegol in intermediate AMD are based on results from post-hoc analyses of data from our GATHER1 trial. Although there is scientific literature supporting the potential use of complement system inhibitors for the treatment of intermediate AMD, we have not yet conducted a clinical trial assessing avacincaptad pegol in patients with earlier stages of AMD. Intermediate AMD is a developing field of study whose patient population continues to be defined by the medical community, and as such, the patient population and primary endpoint we choose for any clinical trial we undertake may not be accepted by regulators. We are continuing discussions with the FDA regarding our development plans and strategy for this important patient population. We may also decide to pursue clinical development of avacincaptad pegol for other indications, including those we previously studied such as wet AMD and IPCV. Similar to GA and STGD1, avacincaptad pegol, and the use of C5 inhibition, are unproven in those indications and we may not be successful in our efforts to develop avacincaptad pegol for those indications.

The GATHER2 trial may yield 24-month results that are different from the positive 12-month results we observed or the results from the GATHER1 trial. Additionally, the OLE study may yield safety results that are different from the safety data we have to date for avacincaptad pegol.

The positive 12-month results we observed from the GATHER2 trial may not be consistent with the 24-month results of this trial. In accordance with the GATHER2 trial protocol, we will continue to treat and follow patients through the 24-month time point to collect additional data. These data may indicate an unexpected or unknown safety issue, including increased incidence of CNV, or may indicate a different efficacy profile for avacincaptad pegol during the period between month 12 and month 24. After month 24, we expect to receive and analyze individual patient data on an unmasked basis following completion of the trial by all patients. We expect that the unmasked individual patient data will provide us a better understanding of the results and the variables affecting the results, although it may indicate that our initial conclusions were not well founded due to inconsistencies, data entry errors or because of unknown variables or patient sub-groups that could potentially be driving the results in either the avacincaptad pegol 2 mg group or the sham control group. Additionally, patients may drop out from the trial or miss visits between month 12 and month 24 in a greater number than we expect, which could also hamper our ability to draw conclusions from the 24-month data. If the month 24 results are inconsistent with the month 12 results, it may affect our ability to commercialize avacincaptad pegol for GA.

Additionally, for our GATHER2 trial, we have re-randomized the patients in the monthly avacincaptad pegol 2 mg treatment arm at 12 months and are evaluating dosing avacincaptad pegol 2 mg every other month, a dosing regimen which we have not previously studied, in half of those patients during the second 12 months of the trial. The GATHER2 trial, however, is not designed to assess any differences we observe between these treatment groups at 24 months with statistical significance and the label we would seek for avacincaptad pegol in GA will be based on the primary endpoint at 12 months and in all likelihood provide for monthly administration of avacincaptad pegol.

We are conducting the GATHER2 trial at many clinical trial sites and in many countries that were not included in the GATHER1 trial. The introduction of new sites, as well as the resulting different patient demographics, have resulted in additional variability in the conduct of the trial and variability of patient outcomes. For example, although we observed a 14.3% reduction in the mean rate of growth (slope) in GA area between the avacincaptad pegol 2 mg group and sham control group at 12 months across the entire trial using the primary analysis, in a post-hoc analysis of U.S. only patients, we observed a 25.5% reduction. We may encounter additional variations as we continue to analyze the data.

Unlike the GATHER1 or GATHER2 trials, 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. The safety results from the OLE study may be different from the safety results we have to date for avacincaptad pegol.

If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of such product candidates. There are a number of known safety risks associated with our product candidates and currently unknown safety issues may arise during development.

If any of our product candidates are associated with serious adverse events or undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many drugs that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development or future commercialization. Safety issues may arise due to reasons unrelated to the study drug, such as issues with the injection procedure or the syringes or needles being used.

We observed an increase in the number of investigator-reported cases of CNV in the avacincaptad pegol treatment groups in the completed GATHER1 trial as compared to the sham control groups. In the ongoing GATHER2 trial, we have observed a higher rate of CNV cases in the avacincaptad pegol 2 mg treatment group as compared to the sham control group at 12 months. We have no unmasked data regarding the safety, tolerability or efficacy of avacincaptad pegol administered for the treatment of STGD1. We have no human data regarding IC-500.

Our clinical trials for avacincaptad pegol involve dosing regimens that we have not studied extensively, which may increase the risk that patients in these trials experience adverse events and/or serious adverse events (either ocular, systemic or both) that we have not observed or at rates that we have not observed in prior trials. For example, although we view the rate of CNV incidence in the avacincaptad pegol treatment groups, as compared to the corresponding sham control groups, as acceptable and within the range observed in other clinical trials of complement inhibitors in development for GA, the FDA, EMA, other regulatory authorities, treating physicians or patients may not agree, concluding that avacincaptad pegol may increase the risk of patients developing CNV to an unacceptable degree. Moreover, our clinical trials for avacincaptad pegol involve multiple intravitreal injections over an extended period of time and, as such, may involve risks involved with multiple and chronic intravitreal injections. For these reasons, there may be, among others, an increase in the rates of intraocular infections, or endophthalmitis, intraocular pressure, glaucoma, retinal tears, cataracts, retinal detachment, intraocular inflammation, retinal and/or choroidal circulation compromise, or hospitalizations in patients who receive avacincaptad pegol. Although we have observed no events of endophthalmitis, no intraocular inflammation events, no events of vasculitis and no ischemic optic neuropathy events through month 12 in GATHER2, these events may occur in the second half of the trial or in the OLE study. An unforeseen or unexpected safety event, or any safety finding that is inconsistent with our prior experience with avacincaptad pegol, from any of our clinical trials for avacincaptad pegol, including from the GATHER2 trial during which we will follow patients and collect safety data over 24 months or the OLE study during which we will follow patients and collect safety data for up to an additional 18 months, may impact the long-term viability of avacincaptad pegol as a potential treatment for GA, intermediate AMD, STGD1 or any other indication for which we may seek to develop avacincaptad pegol.

As HtrA1 inhibition is a novel treatment approach for treating ocular disease, this treatment approach may present potentially unknown safety risks when tested in clinical trials that could not have been anticipated based on preclinical studies. In addition, we intend to administer IC-500 by intravitreal injection, which poses the same safety risks outlined above with respect to intravitreal injections of avacincaptad pegol.

In addition, there are several known safety risks specific to gene therapy, including inflammation resulting from a patient's immune response to the administration of viral vectors and the potential for toxicity as a result of chronic exposure to the expressed protein. Managing a host body's immune response to introduced viral vectors has been and remains a challenge for gene therapies. For AAV gene therapy, “vector shedding,” or the dispersal of AAV vectors away from the target tissue to other parts of the body, which can trigger a more serious and extensive immune response, is a known safety issue. Although subretinal injection, which is the method often used to administer retinal gene therapies, helps to control vector shedding beyond the eye, subretinal injection is a surgical procedure that requires significant skill and training for the administering surgeon and involves its own risks separate from the gene therapy vectors, including the risk of retinal detachment. The margin for error with subretinal injections is extremely low and there are a limited number of retinal surgeons with experience in performing subretinal injections in the eye. In order to generate useful clinical data for gene therapy clinical trials, one or more retinal surgeons must repeat the same subretinal injection procedure in multiple patients with consistency across patients and surgeons. In the event that we progress into clinical development with a gene therapy product candidate, we may experience delays or other challenges for our gene therapy development programs as a result of safety issues.

In addition to the currently known safety risks, there may be unknown risks to human health from gene therapies. Because gene therapy involves the introduction of concentrated quantities of AAV, as well as the introduction of persistent foreign genetic material into the human body, any safety risks may not manifest until much later, if at all. Gene therapies have only recently been used in the treatment of human diseases and the scientific and medical understandings of safety or other risks to humans continue to evolve. The safety profile of minigenes and their associated proteins in humans remains largely unknown.

If gene therapies prove to be unsafe for humans, we likely will need to curtail or eliminate our gene therapy development programs.

We have no unmasked clinical data regarding the safety and efficacy of avacincaptad pegol as a treatment of STGD1. The dropout rate or patients with missing visits may reduce the number of patients from whom we can collect and analyze data from STAR. We may not be able to recruit additional patients for this trial in line with our expectations.

We have no unmasked clinical data regarding the safety and efficacy of avacincaptad pegol as a treatment for STGD1. As STGD1 is an orphan indication, to our knowledge there is only very limited natural history data currently available regarding the variability of our planned primary efficacy endpoint in the STGD1 patient population we enrolled in this trial. Moreover, because Stargardt disease, like GA, is a degenerative disease, and in many cases, the rate of degeneration is slow, and because we are seeking to slow the progression of degeneration with avacincaptad pegol, and not necessarily to reverse prior degeneration or restore visual function, patients participating in our STAR trial, who are generally younger and may experience vision loss that is more subtle than patients with GA or other forms of AMD, may not perceive a benefit from enrolling or continuing to participate and therefore may drop out of this trial or miss scheduled visits and treatments. Although we and the investigators and their staffs take efforts to encourage continued patient participation, the dropout rate may exceed our expectations. A higher than expected dropout rate would reduce the number of patients from whom data is available for analyzing the primary endpoint for this trial. Given the information above, our STAR trial could be underpowered to demonstrate a potential clinical benefit for avacincaptad pegol in STGD1 with statistical significance.

We have decided to enroll approximately 25 additional patients in this trial, with the goal of enrolling a total of approximately 120 patients. This change to the trial has increased the costs associated with this trial and has delayed the timelines for receipt of data from this trial. We believe an expanded trial could allow us to collect additional data regarding the effect of avacincaptad pegol on STGD1 patients and help us mitigate the risks from additional patient dropouts and missed visits; however, these expectations may prove to be incorrect. We are continuing to recruit and enroll patients in this trial. Patient recruitment may take longer or cost more than we would expect.

The COVID-19 pandemic has affected and may continue to affect the initiation and conduct of our clinical trials, including the retention of patients for our GATHER2 clinical trial and patient recruitment and retention for our STAR clinical trial and the OLE study. It may have long-lasting effects on the conduct of clinical trials, which can make our ongoing and any future trials more difficult, costly or time consuming.

Our GATHER2 and STAR trials and the OLE study involve sites located across the United States and in many countries outside the United States. At the start of the COVID-19 pandemic in early 2020, we were conducting startup activities for the GATHER2 trial, and we were in the process of completing patient visits for our GATHER1 trial and those of the initially enrolled patients in the STAR trial. We made a number of operational changes to our clinical trials as a result of the COVID-19 pandemic, its effects on current and prospective participating patients, and various governmental and other measures in response to the pandemic. As the COVID-19 pandemic evolves, we may make further changes to how we conduct our ongoing and any future clinical trials.

Patient enrollment, missed patient visits and patient retention remain key risks for our clinical trials. Due to the COVID-19 pandemic, we delayed the initiation of patient enrollment for the GATHER2 trial from March 2020 to June 2020. We are continuing to enroll patients in the STAR trial and the recently initiated OLE study, where we may choose to or be required to slow down or stop patient enrollment in certain geographies due to the COVID-19 pandemic and any governmental measures taken in response. Patients, in turn, may be reluctant to enroll in clinical trials or to maintain their scheduled visits and treatments once enrolled due to their reluctance to visit clinical trial sites for fear of potential exposure to COVID-19 or ongoing restrictive measures requiring social distancing or limiting travel. These concerns may particularly apply to GA patients, many of whom are elderly and therefore at a higher risk for COVID-19 and other diseases than the general population.

For patients who are enrolled in our trials, the COVID-19 pandemic may cause them to miss study visits or drop out in greater numbers than expected, which could affect our ability to complete our trials and obtain data in accordance with our expectations. Compared to the generally elderly patients in our GATHER2 trial, the patients in the STAR trial are generally younger and have work and family commitments, which may cause them to miss more visits or drop out in greater numbers. In addition to the risks posed by increased patient dropouts, if patients miss scheduled visits in greater numbers as a result of the pandemic, especially if a patient misses consecutive visits, it may affect our ability to draw meaningful conclusions from the clinical data. We are aware that a number of patients initially enrolled in the STAR trial missed consecutive visits during the early months of the COVID-19 pandemic and that a number of patients in our Latin America sites for GATHER2 missed visits because of the COVID-19 pandemic. We do not know yet whether the number of missed visits will increase or decrease in any of these trials, and whether and to what extent missed visits may impact patient retention in these trials or the results of the

trials, especially since we are masked to the data until the conclusion of the trials. The duration of the GATHER2 and STAR trials, and of the OLE study, at 24 months, 18 months and 18 months, respectively, plus time for recruiting patients, makes them more likely to be affected by any subsequent waves of the COVID-19 pandemic.

The COVID-19 pandemic initially caused many of our clinical trial sites and competent health authorities and ethics committees in certain countries to reduce their staff and operations. In 2020, this reduction in operations resulted in delays to the approval of and the site activation process for the GATHER2 trial in certain geographies. During late 2020 to early 2021, a number of our clinical trial sites scaled back their operations because of surges in COVID-19 cases or new lockdown measures being imposed. If any reductions in staff and operations recur or persist at our clinical trial sites, it may affect our conduct of the ongoing GATHER2 and STAR trials and the OLE study. Shortages of vaccines, personal protective equipment and other supplies for the prevention of COVID-19 and the proliferation of new variants of COVID-19 may cause our clinical trial sites to further scale back the number of staff on site and other operations, and may also cause prospective or enrolled patients to avoid clinical trial visits.

In addition to the disruptions to the operations of many clinical trial sites, the COVID-19 pandemic affected our monitoring and audit operations, for example, by requiring remote monitoring, remote source document verification and remote auditing in many instances. Some countries prohibit or limit remote source document verification due to privacy and other concerns. During 2020 and early 2021, we experienced difficulties and delays in performing audits on most of our clinical trial sites because of privacy and other concerns with remote auditing. Although we do not believe the COVID-19 pandemic has materially affected the robustness of our data verification process for the GATHER1 or GATHER2 trials, we or regulatory authorities may find data verification discrepancies upon reviewing the data from the trials. This risk may also affect our data verification processes for the STAR trial or the OLE study.

Our development of IC-500 is also based on a novel mechanism of action that is unproven and poses a number of scientific and other risks.

IC-500, our selected product candidate from our HtrA1 inhibitor program, is in preclinical development. There are no FDA or EMA approved products that utilize HtrA1 inhibition as a mechanism of action for treating ophthalmic diseases, including GA and other age-related retinal diseases for which we may develop IC-500, and this mechanism of action may not prove safe and effective for these diseases. Although we are aware that a few other companies are pursuing HtrA1 inhibition as a strategy for treating retinal diseases, to date, there is limited published clinical data regarding the safety and efficacy of HtrA1 inhibition in the target patient population. We are also aware that Genentech was conducting a Phase 2 clinical trial for its monoclonal antibody HtrA1 inhibitor but recently discontinued that trial. We made the decision to acquire our HtrA1 inhibitors program in 2018 based on our interpretation of the scientific literature and rationale for this potential target that suggest an association between HtrA1 and the risk for AMD, as well as a limited set of preclinical data generated by Inception 4 prior to the acquisition. Even though genetic and histologic findings correlate HtrA1 with AMD, the development and progression of AMD may not be affected by HtrA1 or may be more strongly affected by other genes. Our hypothesis that targeting inhibition of HtrA1 may be a safe and effective method of treating AMD may ultimately be incorrect, which would likely adversely affect the value of IC-500 and its continued development.

To our knowledge, there are no suitable animal models for GA or dry AMD. This absence of a suitable animal model makes designing a proof of concept study to assess the preclinical efficacy of IC-500 difficult. To date, we have only generated limited preclinical data of IC-500 in animal studies and we are conducting and planning additional studies to assess the pharmacokinetics and toxicology of IC-500 in animals, which ultimately may fail to produce favorable results. In addition, we have not had any formal or informal interactions with the FDA or other regulatory authorities regarding our development plans for IC-500. We do not know whether the FDA or other regulatory authorities will accept any preclinical proof of concept study we may propose, or other aspects of our development plans for IC-500. The FDA may require us to change our plans or conduct additional studies, which would increase our costs and delay our timelines.

Gene therapy is an emerging field of drug development that poses many scientific and other risks. We are refocusing our gene therapy development efforts from IC-100 and IC-200 to earlier stage research programs, and need to continue building our gene therapy capabilities. Our limited experience with gene therapy and the limited patient populations for our gene therapy programs may limit our ability to be successful or may delay our development efforts.

Gene therapy is an emerging field of drug development with only a small number of gene replacement therapies having received FDA approval to date. Our gene therapy research and development programs, which we decided to undertake based on a review of a limited set of preclinical data, are still at an early stage. Even with promising preclinical data, there remains several areas of drug development risk, including translational science, manufacturing processes and materials, safety concerns, regulatory pathway and clinical trial design and execution, which pose particular uncertainty for our programs given the

relatively limited development history of, and our limited prior experience with, gene therapies. For example, we observed inconclusive data across the two preclinical toxicology studies we conducted for IC-100, which caused us to evaluate our development options for this product candidate. Furthermore, the medical community's understanding of the genetic causes of many diseases continues to evolve and further research may change the medical community's views on what therapies and approaches are most effective for addressing certain diseases.

For our miniCEP290 program and other minigene programs, we are pursuing research using a novel approach that is largely untested and presents various scientific and regulatory risks. To date, all the data generated for our miniCEP290 and miniABCA4 programs are in mice models for LCA10 and STGD1, respectively, and we do not know whether the effect we observed with these minigenes in mice will be replicated in other animals or humans. Furthermore, minigenes result in the expression of a protein that differs from the naturally occurring protein. The protein expressed by the minigene may have physiological effects, including toxic effects, that are not yet known. Because of the novelty of minigenes, the medical community's and regulators' receptiveness to this approach remains unknown. Our research efforts may not fully elucidate all of the physiological risks associated with a particular minigene and the associated expressed protein. For these and other reasons, promising minigene candidates that emerge from our gene therapy research programs may not succeed in later stage preclinical and clinical development.

We have particularly focused on AAV gene therapy, as AAV vectors are relatively specific to retinal cells and their safety profile in humans is relatively well-documented as compared to other delivery vehicles and gene therapy technologies currently in development. However, AAV has a number of drawbacks, including its small packaging capacity: an AAV vector can hold only up to approximately 4,700 base pairs of DNA, whereas the genes that are associated with a number of diseases, such as LCA10, Stargardt disease and Usher 2A, exceed that size. Although AAV is the most commonly used vector in ocular gene therapy today, it may prove to pose safety risks that we are not aware of and other vector forms, such as retroviral or lentiviral and non-viral based vectors, or gene editing approaches, may prove to be safer and more effective.

As we pursue our gene therapy research programs, we expect we will need to continue to grow our own gene therapy scientific and technical capabilities through hiring internally and seeking assistance from outside service providers. We believe that gene therapy is an area of significant investment by biotechnology and pharmaceutical companies and that there may be a scarcity of talent available to us in these areas. If we are not able to expand our gene therapy capabilities, we may not be able to develop in the way we intend or desire any promising product candidates that emerge from our gene therapy research programs.

We have not previously conducted any clinical development involving gene therapies and, if and when we are ready to conduct our first gene therapy clinical trial, we will need to build our internal and external capabilities in designing and executing a gene therapy clinical trial. There are many known and unknown risks involved in translating preclinical development of gene therapies to clinical development, including selecting appropriate endpoints and dosage levels for dosing humans based on preclinical data. Many of the indications for which we are pursuing our gene therapy programs have limited natural history data and limited number of therapies in clinical development, which may make selecting an appropriate endpoint difficult. Furthermore, our gene therapy programs are targeting orphan diseases with relatively small populations, which limits the pool of potential patients for our gene therapy clinical trials. Because gene therapy trials generally require patients who have not previously received any other therapy for the same indication, we will also need to compete for the same group of potential clinical trial patients with our competitors who are also developing therapies for these same indications. If we are unable to initiate and conduct our gene therapy clinical trials in a manner that satisfies our expectations or regulatory requirements, the value of our gene therapy programs may be diminished.

For a further discussion of the risks associated with the manufacturing of gene therapy products, see the risk factor herein entitled "*The manufacture of gene therapy products is complex with a number of scientific and technical risks, some of which are common to the manufacture of drugs and biologics and others are unique to the manufacture of gene therapies.*"

Ethical, legal and social issues related to genetic testing may reduce demand for any product candidates that require genetic testing for use.

For certain of our product candidates, including any promising candidates from our gene therapy research programs, we may require that as part of participating in a clinical trial or determining eligibility for that product candidate, patients undergo genetic testing. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. The ownership of and the lawfulness of using genetic data is an area of the law that is unclear and varies across jurisdictions. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. For example, concerns have been raised that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This dynamic could lead to governmental authorities restricting genetic testing or

calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure, as well as the use of genetic data. Any of these scenarios could decrease the pool of patients willing to participate in a clinical trial or receive a product candidate for which we require genetic testing.

Risks Related to Our Dependence on Third Parties

We contract with third parties for the manufacture of and for providing starting materials for our product candidates for preclinical development activities and clinical trials and expect to continue to do so in the future, including to support potential commercialization of avacincaptad pegol. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or product candidates of sufficient quality, which could delay, prevent or impair our development or commercialization efforts. The COVID-19 pandemic has affected our contract manufacturers' operations and the manufacture of our product candidates.

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We currently rely upon and expect to continue to rely upon third-party contract manufacturers to manufacture preclinical and clinical supplies of product candidates we are developing or may develop and commercial supplies of products if and when approved for marketing by applicable regulatory authorities. Furthermore, we and our contract manufacturers currently rely upon, and for the foreseeable future expect to continue to rely upon, sole-source suppliers of certain starting materials and other specialized components of production used in the manufacture and fill/finish of our product candidates.

We have historically relied on, and purchased on a purchase order basis from, a single third-party manufacturer, Agilent, to provide avacincaptad pegol drug substance. We are working with Agilent and a new manufacturer to conduct scale up and validation activities for avacincaptad pegol drug substance. However, we do not currently have any contractual commitments with Agilent or the new manufacturer for the long-term clinical or commercial supply of avacincaptad pegol drug substance. We have also historically relied on a single third-party manufacturer, Ajinomoto, for avacincaptad pegol drug product. We plan to rely on Ajinomoto for supply of avacincaptad pegol drug product using the new vial for commercial supply upon launch, if approved. However, we may ultimately need to rely on other manufacturers for long-term supply of avacincaptad pegol drug product. We purchase the PEG starting material on a purchase order basis from a single third-party supplier. We are continuing discussions with this supplier for a long-term supply agreement for the PEG starting material. For these and any other manufacturers with which we do not have any contractual commitments for supply, the pricing and other terms for supply may vary, even substantially, over time and could adversely affect our financial results and operations.

For IC-500, we work with a number of CDMOs to conduct process development, scale-up and cGMP manufacture of the drug substance and drug product for preclinical toxicology studies and early-stage clinical trials.

Our current and anticipated future dependence upon others for the manufacture of the product candidates that we are developing or may develop may adversely affect our business plan and future growth. For example, any production constraints, performance failure or differing priorities on the part of our existing or future manufacturers could delay preclinical or clinical development or marketing approval of our product candidates. Our dependence on third party manufacturers may limit our ability to commercialize on a timely and competitive basis any products that receive marketing approval. We may not have adequate or timely visibility over issues at our third-party manufacturers, and may not become aware of any such issues until the effect on our programs, if any, has already materialized.

Over the past few years, Agilent has been undergoing rapid expansion, including ramping up for production for existing clients, bringing on additional clients, opening new facilities, installing and validating new equipment, and hiring and training new personnel. As a result, we engaged a new contract manufacturer for supply of avacincaptad pegol drug substance, which we had planned to be our primary manufacturer for avacincaptad pegol drug substance. We encountered issues during technology transfer of the avacincaptad pegol manufacturing process to this manufacturer, which delayed our timelines with this manufacturer. Subject to successful completion of scale up and validation activities, we currently plan to use Agilent as the primary source of supply of avacincaptad pegol drug substance upon launch, if approved, and the new manufacturer as a second source of supply of avacincaptad pegol drug substance. We are continuing discussions with Agilent for long-term commercial supply of avacincaptad pegol drug substance. In addition, expansion experienced by other manufacturers and suppliers that we use, including any issues that they may experience while expanding, could negatively impact the timing, costs, progress, quality and outcome of our planned manufacturing activities with those manufacturers and delay or hinder our development or commercialization plans.

If any of our third-party manufacturers, fill/finish providers or sole-source suppliers fail to fulfill our contracts or purchase orders, or if any of these manufacturers or suppliers should become unavailable to us for any reason, including as a result of

capacity constraints, differing priorities, regulatory compliance issues, financial difficulties or insolvency, we believe that there are a limited number of potential replacement manufacturers or sole source suppliers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We may be unable to establish agreements with such replacement manufacturers, fill/finish providers or sole-source suppliers or may need to do so under unfavorable terms. Furthermore, there are a limited number of contract manufacturers with experience manufacturing oligonucleotides, which may limit our ability to find and use alternative manufacturers.

As a result of the COVID-19 pandemic, our third-party contract manufacturers and many sole-source suppliers initially limited their operations by reducing the number of staff on site and instituting restrictions on visitors. These changes affected how we work with our manufacturers and resulted in minor delays to the progress of our manufacturing activities. Additionally, shortages and governmental restrictions arising from the COVID-19 pandemic have disrupted and may continue to disrupt the ability of our contract manufacturers to procure items, such raw materials, that are essential for the manufacture of our product candidates. For example, in 2020, the COVID-19 pandemic and governmental measures in response caused a delay to the process development activities at our drug substance manufacturer for IC-500 as a result of difficulty in procuring one of the raw materials used in the manufacture of IC-500 from China. Over the past two years, there have been increasing disruptions in the global supply chain for various materials, due to the effects of the COVID-19 pandemic and other macro-economic events. For example, the new manufacturer we are working with as a second source of supply for avacincaptad pegol drug substance has experienced issues with procuring a number of raw materials due to supply chain interruptions, which caused several delays to our manufacturing timelines with this manufacturer. To date, we have not experienced any drug product supply issues impacting our GATHER2 and STAR clinical trials or the OLE study and we do not believe our overall timelines for avacincaptad pegol have been materially impacted as a result of supply chain issues affecting our contract manufacturers. We continue to monitor our supply chain closely.

In addition, we and our third party manufacturers source some of the raw and starting materials used in the manufacture of our product candidates from outside the United States. We source the PEG starting material from a supplier outside the United States. Our supplier relationships could be interrupted due to international supply disruptions, including those caused by geopolitical and other issues. For example, trade disputes, trade negotiations or the imposition of tariffs between the United States and its trading partners, and other geopolitical events such as the military conflict between Russia and Ukraine and the resulting sanctions imposed by the United States and other governments and any additional future sanctions or actions in response to the military conflict or other geopolitical events, could cause delays or disruptions in our supply of starting materials for our product candidates.

Reliance on third-party manufacturers entails additional risks, including:

- our product candidates may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under cGMP conditions;
- reliance on the third party for regulatory compliance, quality control and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how, or the proprietary information of third parties that we are responsible for protecting; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. As part of seeking marketing approval, we and our third-party manufacturers will be subject to inspections by the FDA and other regulatory authorities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

We plan to rely on third-party commercial distribution and other commercial services vendors to assist us with the development and implementation of our commercial value chain and related services for the potential commercialization of avacincaptad pegol, if approved, and those third parties may not perform satisfactorily, including lacking adequate workforce and capacity for storage and distribution.

We plan to rely on third parties, such as commercial packaging and warehousing providers, third party logistics providers, or 3PLs, specialty distributors and specialty pharmacies, for the storage and commercial distribution of avacincaptad pegol, if approved. We also plan to rely on third party access and reimbursement providers to support patient access and provider reimbursement programs for avacincaptad pegol, if approved. Those third parties may have different business priorities and may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, our commercial value chain could be adversely affected and our commercialization efforts could be delayed.

The COVID-19 pandemic has resulted in persistent global supply chain challenges and logistics backlogs for many industries. Our selected commercial service providers may experience worker shortages, distribution backlogs or other issues that could disrupt our ability to meet product demand Any performance failure on the part of these third parties could delay commercialization of avacincaptad pegol, if approved, and adversely affect our results of operations.

We rely upon third parties in conducting our preclinical development activities and clinical trials, and those third parties may not perform satisfactorily, including failing to follow regulatory requirements or to meet deadlines for the completion of such activities. The COVID-19 pandemic has also affected their operations.

We are relying upon and expect in the future to rely upon third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions (including reading centers) and clinical investigators, in conducting our preclinical testing, analytical testing and clinical trials for our product candidates. We also expect to rely upon certain facilities at UMMS for various services supporting our research and development programs, including maintenance and care of research animals and production of viral vectors. These third parties may also have relationships with other entities, some of which may be our competitors. We or these third parties may terminate their engagements with us at any time for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities could potentially be delayed and could potentially be very costly.

The COVID-19 pandemic caused our university collaborators to limit the number of staff on site and the types of activities that may be conducted in their laboratories. For example, during 2020 UMMS suspended researcher access to their laboratories and the conduct of certain animal studies and reduced the number of staff in its animal medicine department, which delayed our timelines for our miniCEP290 and miniUSH2A sponsored research programs. Shortages and governmental restrictions arising from the COVID-19 pandemic may also disrupt the ability of our academic collaborators, clinical trial sites and other contract research organizations to procure items that are essential for our research and development activities, including, for example, medical and laboratory supplies used in our clinical trials, including personal protective equipment for site staff, or animals that are used for preclinical studies. For example, there have been shortages of various animals used in research studies, such as several types of monkeys, which are typically sourced from China, due to the COVID-19 pandemic and disruptions to the global supply chain. Since last year, several of our vendors have been facing backlogs due to work and demands from other clients, including those who are developing vaccines or medicines for the COVID-19 pandemic, which has limited their availability to perform work for us. Many CROs have limited slots available for preclinical studies and experienced increased absenteeism of staff in wake of the Omicron variant; these factors caused a delay of our previously planned start date for our IND-enabling toxicology studies for IC-500. There is no guarantee that the COVID-19 pandemic will not further impact our third-party vendors, which could have a material impact on our research and development programs.

Our reliance on these third parties for preclinical testing, analytical testing and clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on various government-sponsored databases within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Over the past decade, there has been increasing oversight by the FDA and other regulatory authorities on data integrity, especially in the research and development of novel therapies such as gene therapies. We rely upon the practices of and systems in place at our third party collaborators in generating data to support our preclinical and clinical development programs and for quality control over this data. Their practices and systems vary in scope and effectiveness and we have a limited number of personnel to supervise, including to perform quality assurance of, those practices and systems. In 2020 and early 2021, the COVID-19 pandemic prevented us from performing audits on our vendors and clinical trial sites that we otherwise would have performed, which decreases the level of oversight we have over those vendors and clinical trial sites and increases the risk of

non-compliance. Any failure of such practices or systems to comply with our stated protocols or regulatory requirements could adversely affect the quality of the data generated by these studies. For a number of our analytical development and testing providers, our CDMOs subcontract and manage that work on our behalf and we have less visibility into or control over their activities. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies, analytical testing or clinical trials in accordance with regulatory requirements or our stated protocols, we would not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and would not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely upon other third parties to store, package, label and distribute drug supplies for our clinical trials and to store materials for our development activities. In particular, we rely on a limited number of third parties to store starting materials, drug substance and drug product for our product candidates and programs. Our product candidates are required to be stored and shipped at certain temperatures and a deviation from those requirements may result in delays or additional costs. In addition, a number of these vendors are also servicing other clients who are developing vaccines or medicines for the COVID-19 pandemic and those vendors may prioritize those other clients over us. Any performance failure on the part of these third parties could delay preclinical development, clinical development or marketing approval of our product candidates or commercialization of our products and adversely affect our results of operations.

We have historically relied upon third-party researchers to advance our sponsored research programs. We may not be able to fully realize the benefits of any intellectual property generated by these arrangements.

Part of our strategy to date involves collaborative sponsored research performed by third-party research institutions. Although we have sought to direct this research and advise on the design of these projects as well as critical development decisions, this research has been performed by individuals who are not our employees and the timeline and quality of the research efforts are outside of our direct control. Academic investigators and other researchers may have different priorities than we do as a biopharmaceutical drug development company. The sponsored research agreements we have entered into for these programs generally provide that any inventions resulting from the research will be owned by the research institution performing the research, and that we have an option to negotiate for a license to develop and exploit any such inventions. If we exercise our option rights for a program that is attractive to us, we may not be successful at in-licensing rights to the inventions or may need to agree to unfavorable terms.

Confidential information and new inventions derived from these research efforts may be disclosed through publications or other means prior to us or our third-party research collaborators being able to protect such intellectual property through the filing of patent applications. Our third-party research collaborators may not be able to obtain or maintain full ownership of inventions that are derived from the research or associated rights, which may limit their ability to provide us with a license to all relevant intellectual property on terms and conditions that are acceptable to us. Even if our collaborative research efforts yield promising results or new technological advances, they may not ultimately result in our being able to protect, develop or exploit the resulting intellectual property.

We transitioned the miniCEP290, miniABCA4 and miniUSH2A research programs from UMMS to us. Those programs were previously collaborative sponsored research programs overseen by researchers at UMMS, and we are continuing those research programs internally. As part of this transition, we needed to obtain or breed new animals for the miniABCA4 program and the miniUSH2A program, which led to delays in our timelines for receipt of data from both programs. We may not be successful in pursuing these research programs internally.

We may seek a collaborator for the further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States. We are currently planning to seek a collaborator or licensee for the further development of IC-100 and/or IC-200. If we are not able to establish collaborations to advance these or any of our other development programs, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates is likely to require substantial additional cash to fund expenses and the hiring of additional qualified personnel. In addition, the development or commercialization of a product candidate in markets outside of the United States requires regulatory expertise and commercial capabilities that are specific to the local market. A number of countries require sponsors to perform a clinical trial in the local jurisdiction or with patients similar to the demographics of the local population as a condition to approving the drug. For some of our product candidates, we may seek to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. In particular, we may seek a collaborator for the further development and potential commercialization of avacincaptad pegol in one or more territories outside the United States. We are currently planning to seek a collaborator or licensee for the further development and potential commercialization of IC-100 and IC-200.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials and other data we have generated for the product candidate, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, any patent or other forms of exclusivity for such product candidate and the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the ability to obtain governmental approval for the collaboration, if necessary, and industry and market conditions generally. For a potential collaborator for a sustained release delivery technology for avacincaptad pegol, those factors may include an assessment of the technical feasibility of the technology using the data we and the potential collaborator have generated, which may be preliminary and limited. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. For our gene therapy programs including IC-100 and IC-200, we are party to in-license agreements that limit who we can collaborate with or may require the approval of our licensor for us to enter into a collaboration, and any future license agreements that we may enter into may have similar restrictions. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among pharmaceutical and biotechnology companies over the past decade that have resulted in a reduced number of potential future collaborators and this trend is likely to continue.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop those product candidates or bring them to market and generate product revenue in line with our expectations. For avacincaptad pegol, if we choose to and are unable to find a collaborator for potential commercialization outside the United States, we likely will need to raise additional capital, hire additional personnel and undertake the effort ourselves, any of which may be unsuccessful. In addition, although we currently intend to commercialize avacincaptad pegol in the United States ourselves, if approved, as part of the process for finding a collaborator for potential commercialization in one or more territories outside the United States, we may choose to grant a potential collaborator co-commercialization or co-promotion rights in the United States.

If we enter into collaborations with third parties for the development or commercialization of our product candidates, any such collaborations will carry numerous risks. If any of our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to develop or commercialize our product candidates, either in the United States, or in markets outside the United States. We also may seek third-party collaborators for development and commercialization of other product candidates we may develop, including sustained release delivery technologies for avacincaptad pegol. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any arrangements with third parties, we would likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators, including marketing and distribution collaborators, have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;

- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, changes in product candidate priorities or available funding or changes in priorities as a result of a merger, acquisition or other corporate restructuring or transaction;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may make pricing, reimbursement and commercial decisions that adversely impact or reduce our flexibility to employ pricing, reimbursement and commercial strategies in other geographies, including the United States;
- we could grant exclusive rights to our collaborators, which would prevent us from collaborating with others;
- we may be obligated to supply the collaborator with drug substance or drug product in an amount sufficient for its needs, or may be dependent on the supply of certain materials or products by the collaborator;
- disagreements or disputes with collaborators, including disagreements or disputes over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities for us with respect to product candidates or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive, and be uncertain in outcome;
- collaborators may not properly maintain or defend our intellectual property rights, may infringe the intellectual property rights of third parties, may misappropriate our trade secrets or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation and potential liability;
- laws or practices in certain foreign jurisdictions may require that as a condition of working with a collaborator in such jurisdiction, we agree to certain foreign ownership restrictions, use certain local services or providers, share or license certain of our proprietary information or technology or agree to other conditions that are not attractive to us; and
- collaborations may be terminated at the convenience of the collaborator, our breach of the terms of the collaboration or other reasons and, if terminated, we may need to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If a collaborator of ours were to be involved in a business combination or other transaction, the foregoing risks would be heightened, and the business combination or transaction may divert attention or resources or create competing priorities. The collaborator may delay or terminate our product development or commercialization program. If one of our collaborators terminates its agreement with us, we could find it more difficult to attract new collaborators and the perception of our company could be adversely affected.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We depend on licenses and sublicenses for development and commercialization rights to avacincaptad pegol, IC-100, IC-200 and our miniCEP290 program. These license arrangements, as well as the Inception 4 Merger Agreement, impose diligence obligations on us. We depend on research licenses from UMMS for our miniABCA4 and miniUSH2A programs. We may enter into similar arrangements for future product candidates or technologies. Termination of licenses or the failure by us or our licensees, including our potential future commercialization or collaboration partners, to comply with obligations under these or other agreements could materially harm our business and prevent us from developing or commercializing our products and product candidates.

We are party to a license agreement with Archemix on which we depend for rights to avacincaptad pegol. We are party to the DelSiTech License Agreement with DelSiTech for rights to develop and commercialize new formulations of avacincaptad pegol using DelSiTech's silica-based sustained release delivery technology. We are party to two different license agreements, each with UFRF and Penn, on which we depend for rights to IC-100 and IC-200. We are also party to a license agreement with UMMS for our miniCEP290 program. These agreements generally impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Generally, the diligence obligations contained in these agreements require us to use commercially reasonable efforts to develop, seek regulatory approval for and commercialize the applicable product candidate in the United States and certain territories outside of the United States, including the European Union, Japan and such other markets where it would be commercially reasonable to do so. For IC-100, IC-200 and our miniCEP290 program, we are party to agreements with academic institutions, and under those agreements, we must meet certain milestones by certain timelines and if we fail to do so, we may need to expend significant amounts of money to extend those timelines or otherwise be in breach of those agreements. For example, for IC-100 and IC-200, those milestones include two separate development milestones, which we did not meet at their original respective deadlines. We were able to successfully obtain extensions to those milestones and all subsequent milestones in the RHO-adRP License Agreement and BEST1 License Agreement. If we are unable to meet the extended deadlines for IC-100 or IC-200, or any other diligence milestone timelines in our agreements with our academic licensors, the applicable licensor would have the right to terminate the license agreement on which we depend for rights to IC-100, IC-200 or our miniCEP290 program and we could lose our rights to develop and market IC-100, IC-200 or any product candidates from our miniCEP290 program, or to have a potential collaborator or licensee do so.

Under the license agreements for our product candidates, we generally would not be able to avoid our payment obligations even if we believed a licensed patent right was invalid or unenforceable because the license agreements provide that our licenses to all licensed patent rights would terminate if we challenge the validity or enforceability of any licensed patent right. The Inception 4 Merger Agreement, pursuant to which we acquired IC-500, also imposes specified diligence and milestone payment obligations on us. We may enter into acquisition or licensing agreements in the future that could impose similar obligations on us.

We are also party to research licenses with UMMS for rights to continue with the research and development of our miniABCA4 and miniUSH2A programs. The term of these research licenses is the same as the term for us to exercise our rights under option agreements pursuant to which UMMS granted us option rights to in-license certain patent applications covering these programs. If we fail to exercise our option rights or fail to agree to terms with UMMS for a license for further development and commercialization of the applicable program, we may lose our rights to continue with conducting research and development of that program.

If we fail to comply with our obligations under current or future acquisition and licensing agreements, or otherwise breach an acquisition or licensing agreement as a result of our own actions or inaction or the actions or inactions of our commercialization or collaboration partners, our counterparties may have the right to terminate these agreements, in which event we might not have the rights or the financial resources to develop, manufacture or market any product that is covered by these agreements. Our counterparties also may have the right to convert an exclusive license to non-exclusive in the territory in which we fail to satisfy our diligence obligations, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or restated agreements with less favorable terms, seek alternative sources of financing or cause us to lose our rights under these agreements, including our rights to avacincaptad pegol, DelSiTech's sustained release delivery technology, IC-100, IC-200, our miniCEP290 program, and other important intellectual property or technology. Any of the foregoing could prevent us from commercializing our product candidates, which could have a material adverse effect on our operating results and overall financial condition. In the case of our limited diligence obligation under the Inception 4 Merger Agreement, a potential breach of our obligation to use commercially reasonable efforts to develop an HtrA1 inhibitor could lead to a lawsuit with the former equity holders of Inception 4 and result in potential liability to us of up to $5.0 million.

In addition to the above risks, certain of our intellectual property rights are sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of their upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop, manufacture and commercialize the relevant product candidates may be materially harmed. While the applicable agreements may contain contractual provisions that would in many instances protect our rights as a sublicensee in these circumstances, these provisions may not be enforceable and may not protect our rights in all instances. Further, we do not have the right to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even

when we do have such rights, we may require the cooperation of our licensors and their upstream licensors, which may not be forthcoming. Our business could be materially adversely affected if we are unable to prosecute, maintain and enforce our licensed and sublicensed intellectual property effectively.

Moreover, the license agreements for IC-100, IC-200 and our miniCEP290 program and the research licenses for our miniABCA4 and miniUSH2A programs reserve for the licensing academic institutions the right to continue to practice for research and educational purposes, the inventions covered by the intellectual property rights that we have in-licensed. These licensing institutions or their collaborators may generate scientific, preclinical or clinical data with respect to our product candidates, separate from our research and development efforts, that is inconsistent with other data for such product candidates, including additional preclinical and clinical data that we develop. Investigators at these institutions may publish, present, or otherwise publicly disclose this data, which may have an adverse impact on the prospects of the development of our product candidates and may harm our business. In addition, these institutions may use these data to support new patent applications which could result in the issuance of patents that may limit our freedom to operate without our obtaining additional licenses to these newly developed inventions.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain or do not maintain patent protection for our technology and products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

We currently rely on and expect to continue to rely on patent rights to protect our competitive position. Once our patents expire, we may not be able to exclude competitors from commercializing products similar or identical to ours. The U.S. patent rights covering avacincaptad pegol as a composition of matter are expected to expire in 2025. The U.S. patent rights covering methods of treating certain complement protein mediated disorders with avacincaptad pegol are expected to expire in 2026. The recently issued U.S. patent rights covering methods of using avacincaptad pegol to treat GA are expected to expire in 2034. The European patent rights covering the composition of matter of avacincaptad pegol and methods of treating certain complement protein mediated disorders with avacincaptad pegol are expected to expire in 2025. The patents covering avacincaptad pegol may expire before the date by which we or a potential commercial partner would be able to commercialize avacincaptad pegol in the United States or Europe if we seek and obtain marketing approval. Even if we are able to obtain marketing approval for and commercially launch avacincaptad pegol prior to the expiration of these patents, the remaining term of those patents may be shorter than we anticipate. If we are successful in developing a sustained release delivery technology for avacincaptad pegol, we may be able to obtain patent protection for avacincaptad pegol with the sustained release delivery technology beyond the current patent life for avacincaptad pegol; however, obtaining the additional patent protection from these efforts or other efforts to extend the patent life of avacincaptad pegol is not guaranteed. Although the patent rights under existing patent applications for IC-500, IC-100, IC-200 and our miniCEP290 program are not expected to expire until 2037 or after, we face the same risk with those product candidates and programs and any future product candidates that we may develop.

In March 2022, the USPTO issued a patent with claims covering methods of using avacincaptad pegol to treat GA, which is a method-of-treatment patent. Certain of our licensed patent rights for avacincaptad pegol and IC-100 are method-of-treatment patents and patent applications. Our licensed patent rights for IC-200 are method-of-treatment patent applications. Method-of-treatment patents are more difficult to enforce than composition-of-matter patents because of the risk of off-label sale or use of a drug for the patented method. The FDA does not prohibit physicians from prescribing an approved product for uses that are not described in the product's labeling. Although off-label use of a product may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute. Off-label sales of other products having the same drug substance as our product candidates would limit our ability to generate revenue from the sale of such product candidates, if approved for commercial sale. In addition, patent laws in Europe and some other jurisdictions generally make the issuance and enforcement of patents that cover methods of treatment of the human body difficult in those jurisdictions. Further, once the composition-of-matter patents relating to avacincaptad pegol or IC-100 in a particular jurisdiction, if any, expire, competitors will be able to make, offer and sell products containing the same drug substance as avacincaptad pegol or IC-100 in that jurisdiction so long as these competitors do not infringe any of our other patents covering avacincaptad pegol's or IC-100's composition of matter or method of use or manufacture, do not violate the terms of any marketing exclusivity that may be granted to us by regulatory authorities and they obtain any necessary marketing approvals from applicable regulatory authorities. In such circumstances, we also may not be able to detect, prevent or prosecute off-label use of such competitors' products containing the same drug substance as avacincaptad pegol or IC-100, even if such use infringes any of our method-of-treatment patents.

Depending on potential delays in the regulatory review process for any of our product candidates, we may be able to obtain patent term extension for one of our patents in the United States under the Hatch-Waxman Act, which permits a patent extension term of up to five years as partial compensation for the portion of the patent term effectively lost during product development and the FDA regulatory review process occurring after the issuance of a patent, but we can provide no assurances that such an extension term will be obtained. Similar to the patent term extension available in the United States, the regulatory framework in the European Union and certain other foreign jurisdictions provides the opportunity to extend the term of a patent that covers an approved drug in certain circumstances. Notwithstanding the availability of patent term extension provisions, we may not be granted patent term extensions because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements, such as using diligent efforts to develop a drug candidate. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term or scope of any such extension is less than we request, any period during which we have the right to exclusively market our product would be shorter than we would otherwise expect, and our competitors may commercialize competing products following our patent expiration, and our revenue could be reduced, possibly materially.

The Hatch-Waxman Act also permits the manufacture, use, offer for sale, sale or importation of a patented invention other than a new animal drug or veterinary biological product, if the manufacture, use, offer for sale, sale or importation is solely for uses that are reasonably related to development of information that could be submitted to the FDA. For this reason, our competitors might be able under certain circumstances to perform activities within the scope of the U.S. patents that we own or in-licensed without infringing such patents. This might enable our competitors to develop during the lifetime of these patents drugs that compete with our product candidates.

Our issued patents may not be sufficient to provide us with a competitive advantage. For example, competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Even if our owned or licensed patent applications issue as patents, they may not issue with a scope broad enough to provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, term, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, if we receive marketing approval for our product candidates, other pharmaceutical companies may seek approval of generic or biosimilar versions of our products with the FDA or regulatory authorities in other jurisdictions. We may then be required to initiate proceedings against such companies in order to enforce our intellectual property rights. The risk of being involved in such proceedings is likely to increase if our products are commercially successful. In any such proceedings, the inventorship, ownership, scope, term, validity and enforceability of our patents may be challenged. These and other challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent others from using or commercializing similar or identical technology and products or from launching generic or biosimilar versions of our products, or could limit the duration of the patent protection of our technology and products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patent prosecution process is expensive and time-consuming, is highly uncertain and involves complex legal and factual questions. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates that are important to our business.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify or protect patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we may not pursue or obtain patent protection in all major markets. Moreover, in some circumstances, we do not have the right to control the preparation, filing or prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties or covering technology that a collaboration or commercialization partner may develop, the

eventual commercialization of which could potentially entitle us to royalty payments. In some circumstances, our licensors may have the right to enforce the licensed patents without our involvement or consent, or to decide not to enforce or to allow us to enforce the licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights that we have licensed may be reduced or eliminated and our ability to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, patent laws in Europe and some other jurisdictions restrict the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Moreover, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, term, validity, enforceability and commercial value of our patent rights are highly uncertain.

Our pending and future patent applications, and any collaboration or commercialization partner's pending and future patent applications, may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our or their ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We or any collaboration or commercialization partner may not be able to generate sufficient additional data on a timely basis, or at all. In addition, the issuance of any patents will depend on the existence of any prior art that comes to the patent examiner's attention during prosecution, sometimes through the actions of third parties, and whether our claimed invention meets the statutory criteria for being granted a patent in light of the prior art. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our or a collaboration or commercialization partner's patents or narrow the scope of our or their patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, revised United States patent law in part by changing the standard for patent approval from a "first to invent" standard, which had existed before March 2013, to a "first to file" standard and developing a post-grant review system. For example, if we are the first to invent a new product or its use, but another party is the first to file a patent application on this invention, under the new law the other party may be entitled to the patent rights on the invention.

Moreover, we may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. The Leahy-Smith Act expanded the ability of third parties to challenge the patents held by patentees through administrative reviews at the USPTO, which may facilitate others to challenge our patents. Based on available information, we believe that *inter partes* review proceedings, brought by financial investors who may be selling short the stock of the patent holder, are becoming more prevalent. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights; allow third parties to commercialize our technology or products and compete directly with us, without payment to us; or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to develop or commercialize current or future product candidates.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. For some of our licensed patent rights, we may need the cooperation of our licensors to file such claims. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents

we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. Trademark-related risks are increasing as we work to transition to a commercial-stage pharmaceutical company. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable and we may not be able to obtain injunctive relief. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings or take other actions alleging that we are infringing or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators, including our contract manufacturers and any commercial partners, to develop, manufacture, market and sell our product candidates and products and use our proprietary technologies without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. New patent applications in the field of biotechnology and pharmaceuticals are being filed at a rapid pace.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We or any collaborators may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, re-examination, post-grant review, inter partes review, opposition, cancellation or similar proceedings before the USPTO or its foreign counterparts. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization.

Third parties may assert infringement or other claims against us or our collaborators based on existing or future intellectual property rights. We or they may not be aware of all such intellectual property rights potentially relating to our product candidates and their manufacture, use or sale. In addition, contract manufacturers may inadvertently incorporate intellectual property belonging to third parties into our products or the manufacturing processes for these products without our knowledge. There is a lag between the filing of a patent application, which generally establishes the priority date of a patent claim, and the publication of such patent application. During the period between filing of a patent application and publication of the application, we would not otherwise have a means of discovering the existence or extent of the claimed inventions contained in a filed but unpublished patent application. Patent applications are often drafted broadly, and the scope of patent claims that may ultimately issue may not be known until several years after a patent application is filed and published. We may make development or pipeline decisions based on our belief that our product candidates can be distinguished from patent claims contained in published patent applications or issued patents, that patent claims contained in published patent applications are unlikely to issue as drafted, or that claims contained in issued patents are invalid. These positions regarding third-party intellectual property may not ultimately be successful in litigation. Thus, we do not know with certainty that our product candidates, or our intended manufacture or commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are or any of our collaborators is found to infringe or otherwise violate a third party's intellectual property rights, we or they could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates or products or to continue using a trademark. However, we or our collaborators may not be able to obtain any required license on commercially reasonable terms or at all. Even if we or they were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our collaborators and could require us or them to make substantial licensing and royalty payments. We or our collaborators could be forced, including by court order, to cease using or commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us or our collaborators from making or commercializing our product candidates or force us or them to cease some of our business operations, which could materially harm our business. Claims that we or our collaborators have misappropriated the confidential information or trade secrets of third parties could expose us or them to similar liabilities and have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we or our employees or contractors have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees

and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of such employee's or contractor's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Moreover, because we acquired some of the rights to our product candidates from third parties, we must rely upon these third parties' practices, and those of their predecessors, with regard to the assignment of intellectual property therein, including the intellectual property rights protecting IC-500 and the other HtrA1 inhibitors we acquired in the Inception 4 acquisition transaction. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market sooner than we expect, which would have a material adverse effect on our business.

In addition, we may decide not to pursue patent prosecution in certain markets or jurisdictions. For example, we may decide that the costs of obtaining and maintaining patent protection in a certain jurisdiction may outweigh the commercial benefits of patent protection. If so, our competitors may enter into and commercialize identical or similar products in that jurisdiction and if we choose to commercialize our products in that jurisdiction, we may not be able to exclude our competitors in the same way as if we had chosen to pursue patent prosecution in that jurisdiction.

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

In addition to seeking patents for some of our technology and products, we also rely upon trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our outside scientific collaborators, contract manufacturers, potential business development counterparties, advisors and

other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have executed such agreements with each party that may have or have had access to our trade secrets. Any party with whom we or they have executed a non-disclosure and confidentiality agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not become aware of such breach or may not be able to obtain adequate remedies. As we work on transitioning from a development-stage company to a company capable of commercializing a pharmaceutical product, we are hiring many new employees and engaging additional consultants and service providers, which increases the risk of disclosure or misuse of our proprietary information. Our proprietary information may also be obtained by third parties by other means, such as breaches of our physical or computer security systems.

Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position would be harmed.

Risks Related to Information Technology and Data Protection

We rely significantly upon our information technology systems and any failure, inadequacy, interruption or security lapse of those systems could harm our ability to operate our business effectively. Information technology risks have become more significant over time, including as a result of widespread remote working during the COVID-19 pandemic.

In the ordinary course of business, we collect, process and maintain personal and other sensitive data on our information technology networks. These data include our intellectual property and other proprietary or confidential information relating to our business as well as proprietary or confidential information of third parties including business collaborators. These data also include personal information relating to our clinical trial participants, employees and contractors, clinical investigators and other study staff and healthcare professionals. The secure maintenance of this sensitive information is critical to our business and reputation.

We have implemented a number of measures to protect our information technology systems. These measures include, among others, creation of a cyber-security governance team and an incident response plan and other standard operating procedures for responding to any cyber-security incidents, mandatory routine cyber-security training, including social engineering training, for our employees and consultants with access to our information technology systems, and engagement of a third-party vendor to regularly assess our informational technology systems and potential vulnerabilities.

Despite the implementation of security measures, our information technology systems are vulnerable to compromise, damage, loss or exfiltration from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In particular, companies and other entities and individuals have been increasingly subject to a wide variety of cyber and ransomware attacks, phishing scams and other attempts to gain unauthorized access to systems and information, including through social engineering. The number and complexity of these threats continue to increase over time. These threats can come from a variety of sources, ranging in sophistication from individual hackers to state-sponsored attacks. Cyber threats may be broadly targeted, or they may be custom-crafted against our information systems. In particular, there have been increasing number of cyber threats and attempts by foreign hackers targeted towards U.S. pharmaceutical and biotechnology companies and vendors they work with, including as a result of the ongoing military conflict in Ukraine.

As a result of the COVID-19 pandemic, we switched to remote and hybrid working since March 2020 and as a result, have increasingly relied upon teleconferencing and cloud-based means of communication and data storage. Many other companies have done the same. There have been numerous publicized attempts of bad actors attempting to intercept proprietary communications. We may be similarly susceptible to those kinds of threats.

Cyber-attacks have become more prevalent and much harder to detect and defend against. Our networks and storage applications may be subject to unauthorized access by hackers or breached due to human error, malfeasance or other system disruptions. We may not anticipate or immediately detect such incidents and the damage caused by such incidents. System failures, data breaches and any unauthorized access, use or disclosure of our information or data could compromise our intellectual property and expose sensitive business information; lead to unauthorized exposure of personal information of our clinical trial participants, our employees or contractors, our clinical investigators or other study staff, healthcare professionals or

others we work with; and/or result in disruptions to our research and development activities and business operations, including potential product development, regulatory approval and commercialization delays.

In addition, cyber-attacks and the measures we implement to prevent, detect, and respond to them could cause us to incur significant remediation costs, including costs to recover or reproduce any compromised data, expose us to contractual damages and/or regulatory and other liability, require us to make certain breach notifications, and divert the attention of our management and key information technology resources. Any loss of preclinical data or clinical trial data could result in delays to our product development, marketing approval and commercialization efforts. We may not have adequate insurance coverage to provide compensation for any losses associated with such events and cybersecurity insurance is becoming more expensive. Any breach of security could harm our reputation and deter patients, clinical investigators, or other healthcare professionals and business collaborators from participating in our clinical trials or otherwise working with us.

We also rely significantly upon the information technology systems of our third-party service providers and any failure, inadequacy, interruption or security lapse of those systems could harm our ability to operate our business effectively. We have limited control and oversight over the information security systems and practices of third parties.

In the ordinary course of business, we rely on third parties, including clinical trial sites, CROs, CDMOs and other service providers, to collect, process and maintain personal and other sensitive data on their respective networks for our research and development activities and other business operations. These data include our intellectual property and other proprietary or confidential information relating to our business, as well as personal information relating to our clinical trial participants, employees and contractors, and clinical investigators, study staff and other healthcare professionals. The maintenance of our data by third parties does not absolve us of our responsibility for the security and integrity of this data.

We have limited control and oversight over the information security systems and practices of third parties. Those systems and practices vary widely in sophistication and robustness. We have limited personnel and resources to oversee the information security systems of third parties with whom we work.

Like our information security systems, those of our third-party service providers are vulnerable to compromise, damage, loss or exfiltration from cyber-attacks, computer viruses, unauthorized access and other causes. Our third-party service providers may not anticipate or immediately detect such incidents and the damage caused by such incidents or notify us in a timely or complete manner. System failures, data breaches and any unauthorized access, use or disclosure of our information or data maintained by our third-party service providers could lead to similar consequences for us as similar events involving our information technology systems, including compromise of our intellectual property or other sensitive personal or business information, disruptions and delays to our research and development activities and other operations, contractual and regulatory liability, data breach notifications, expenditure of significant costs and resources for remediation and harm to our reputation. Over the past few years, there has been an increasing number of and severity of cyber-attacks, especially ransomware attacks, against the information security systems of companies across the supply chain and other critical infrastructure service providers.

In September 2020, one of our vendors for the GATHER2 trial suffered a ransomware attack on several of its servers. While this vendor investigated and worked to mitigate the effects of the incident, we deployed a backup process for the work this vendor was performing for us. Although we do not believe this incident had a material impact on the GATHER2 trial or otherwise on our business or operations, similar kinds of incidents may occur in the future with this or our other vendors.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data in line with our expectations, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information is rapidly evolving worldwide and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply, and those frameworks may not be consistent. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities and their rights, conducting data protection impact assessments before starting certain processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party data processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, some of which are currently in flux, and

permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR also provides certain discretion to individual European member states, and many of them have enacted local legislation implementing the GDPR that differ from one another. The GDPR compliance framework is evolving as data protection authorities enforce applicable requirements and as European courts interpret the GDPR. We are aware that many other countries have enacted or are considering legislation similar to the GDPR.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels with the authority to review our privacy and data security practices. The Federal Trade Commission and state Attorneys General have been increasingly active in reviewing companies' privacy and data security practices in relation to consumer information. New legislation and regulations are being considered, and in certain cases enacted, at both the state and federal levels. For example, the California Consumer Privacy Act, which went into effect on January 1, 2020, and its replacement, the California Privacy Rights Act, which will become effective on January 1, 2023, are creating similar risks and obligations as those created by the GDPR. The New York SHIELD Act, which became fully effective in March 2020, imposes certain data security and data breach notification requirements on organizations that collect personal information of New York residents. Many other states are considering similar legislation. A broad range of legislative measures are being introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. We also may be subject to consumer class action litigation related to alleged noncompliance with these laws. Even if we are not determined to have violated these laws, responding to government investigations and/or consumer litigation in these areas typically requires the expenditure of significant resources and has the potential to generate negative publicity, which could harm our reputation and our business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements has required and will continue to require significant time, resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data on our behalf. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, have resulted in certain changes to our business practices, such as additional consideration given to the GDPR and other relevant data protection laws in setting up clinical trial agreements and informed consent forms for our GATHER2 trial, and may require further changes to our business practices. As we set up our commercial infrastructure and practices, we would also need to be mindful of the Health Insurance Portability and Accountability Act, or HIPAA, and its rules and regulations governing protected health information. Any non-compliance by us or our employees, consultants or contractors with the GDPR, HIPAA or other applicable data protection laws could lead to setbacks in the development or approval of our product candidates, government enforcement actions, private litigation, significant fines and penalties, or reputational harm and could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Employee Matters and Managing Our Operations

We are in the process of recruiting new personnel to prepare for the potential commercialization of avacincaptad pegol and to support our growth. We may experience difficulties in recruiting necessary and qualified personnel and in retaining key employees and consultants.

We are currently a development-stage company with a total of 148 full-time employees as of October 31, 2022. These employees support key areas of our business and operations, including commercial planning, clinical development and clinical operations, regulatory affairs, drug safety, data management, biostatistics, medical affairs (including field personnel), scientific research, process and analytical development, drug substance and drug product manufacturing, quality control, materials and supply chain management, and quality assurance, as well as all of our general and administrative functions and public company infrastructure.

We remain highly dependent on Glenn P. Sblendorio, our chief executive officer, and Dr. Pravin U. Dugel, our president, as well as the other principal members of our management, scientific and clinical teams. We do not maintain “key person” insurance for any of our executives or other employees. Although we have entered into letter agreements with our executive officers, each of them and our non-executive employees may terminate their employment with us at any time. As a result, key employees whom we expect to retain to assist with the growth of our business may choose not to remain employees. Additionally, we have only a small number of employees supporting some of the key areas of our business and operations. If any of those employees were to leave our company or become unavailable due to the COVID-19 pandemic or other reasons, the loss of their services could seriously disrupt our ability to carry on our operations as planned and seriously harm our ability to successfully implement our business plan.

Furthermore, replacing any of our executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. As we prepare for the submission of an NDA and an MAA for and the potential commercialization of avacincaptad pegol, and continue the development of IC-500, we have been and expect we will need to continue hiring additional commercial operations, medical affairs, clinical operations, quality assurance, manufacturing, analytical, regulatory, pharmacovigilance and other personnel from this limited pool. Earlier this year, we hired our first group of medical science liaisons, or MSLs and we are starting to recruit and hire a field-based sales force. Hiring field-based personnel, and training and effectively deploying them can be time consuming and expensive, and many other companies are competing with us for the field-based personnel whom we may seek to hire. If we experience any challenges or delays in the hiring and integration of necessary personnel, it could impede our ability to finish development of, file for marketing approval for, and potentially commercialize avacincaptad pegol in line with our expectations.

In addition to our employees, we rely on consultants and advisors, including scientific, technical and clinical advisors, to assist us in formulating our research and development, manufacturing, commercialization and lifecycle management strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Many consultants and advisors, especially those with specialized medical or clinical knowledge, are high demand and we may not be able to obtain or retain their services for any number of reasons, which could limit our ability to pursue our strategy.

As a result of the COVID-19 pandemic, our company has been working remotely since March 2020 and we expect to work in a hybrid (partially remote, partially in office) working model for the foreseeable near future. Our ability to continue to work effectively in a hybrid working model may affect our operations and the success of our company going forward.

In March 2020, we instituted a company-wide working from home policy. Other than for our laboratory-based employees, we expect to work in a hybrid (partially remote, partially in office) working model for the foreseeable near future. We will closely follow the guidance from federal and state authorities, including the Centers for Disease Control and Prevention, the New York State Department of Health, the New Jersey Department of Health and the Massachusetts Department of Public Health, with regard to our policies relating to working in our offices. We expect that changes to the way we work will depend on, among other factors, the local COVID-19 and public safety situation and the degree to which our employees have received vaccines and if applicable, booster shots. As we continue to transition back to working at company sites closer to a full-time basis, there may be an increased risk to our employees and contractors, including as a result of a subsequent waves of the COVID-19 pandemic. If any of them contracts COVID-19 as a result of or while conducting services for us, we may be subject to workers compensation or other claims. Because of the importance of our employees and contractors to the success of our company, their exposure to the COVID-19 pandemic may adversely affect our ability to carry on our operations.

If we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements would not be prevented or detected on a timely basis. If any material weakness in our internal control over financial reporting is discovered or occurs in the future, our financial statements may contain material misstatements and we could be required to restate our financial results. As previously disclosed, in 2015 our management concluded that we experienced a material weakness in internal controls that required us to restate the relevant financial statements and we took steps that year to address the deficiency and prevent similar deficiencies in the future. Although we have remediated this deficiency in internal control over financial reporting, we cannot be certain that the remedial measures that we took in the past or other measures we take in the future will ensure that we maintain adequate controls over our financial reporting going forward and, accordingly, additional material weaknesses could occur or be identified. Any future material weaknesses or combination of deficiencies could materially and adversely affect our ability to provide timely and accurate financial information and investors' confidence in our internal controls and our company, which could cause our stock price to decline.

Risks Related to Legal and Compliance Matters

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we or our third-party commercialization partners may be subject to penalties if we or our third-party commercialization partners or our or their manufacturers fail to comply with regulatory requirements or if we or our third-

party commercialization partners or our or their manufacturers experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we or our commercialization partners obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continued requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control and quality assurance, tracking of complaints and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or may be subject to significant conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the possible requirement to implement a risk evaluation and mitigation strategy.

The FDA, the Federal Trade Commission and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the pre- and post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding preapproval promotion and off-label use and if we engage in inappropriate pre-approval promotion or if we do not market our products for their approved indications, we may be subject to enforcement action. Over the past few years, there has been increasing enforcement activity from the FDA targeting preapproval promotion. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation.

Non-compliance with European Union or other applicable requirements regarding safety monitoring or pharmacovigilance, and with any applicable requirements related to the development of products for the pediatric population, can also result in significant penalties.

Our and our potential commercialization partners' relationships with healthcare professionals, patients and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us and our commercialization partners to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers and third-party payors may expose us and our commercialization partners to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the arrangements and relationships through which we and our commercialization partners market, sell and distribute any products for which we or they obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for benefits, items or services involving a healthcare benefit program;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and providing notifications of the breach of such information, by covered entities and certain business partners;

- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, medical devices and biological products covered by federal healthcare benefit programs to report payments and other transfers of value to physicians, other healthcare providers and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by governmental and non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and may also require the licensing or listing of pharmaceutical sales representatives. State and foreign laws, such as the GDPR, also govern the privacy and security of health information in some circumstances, many of which differ from HIPAA and each other in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. These risks are becoming more important for our operations as avacincaptad pegol advances in clinical development and as we prepare for potential commercialization. We are working to develop and implement a corporate compliance program to ensure that we will market and sell any future products that we successfully develop in compliance with

all applicable laws and regulations, but we cannot guarantee that any such program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our or our commercialization partners' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us or them, we or they may be subject to significant civil, criminal and administrative penalties, including damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our or their operations. If any of the physicians or other healthcare providers or entities with whom we are doing business or expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, and as a result, our relationships with those healthcare providers or third parties may be adversely affected and our business and reputation may suffer.

Current and future healthcare reform legislation may increase the difficulty and costs for us and any future collaborators to obtain reimbursement for any of our product candidates that may receive marketing approval and our ability to generate revenue will be materially impaired.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Other legislative changes have been proposed and adopted since the PPACA was enacted. The Budget Control Act of 2011, among other things, resulted in aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, with passage of the Inflation Reduction Act in August 2022, or the IRA, Congress extended the expansion of PPACA premium tax credits through 2025.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with the enactment of the Tax Cuts and Jobs Act of 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration took executive actions to undermine or delay implementation of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In January 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Executive Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the PPACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the health insurance marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the PPACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and new payment methodologies that govern any of our approved products and/or the level of reimbursement physicians receive for administering any approved products we, or our collaborators, might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates for which we may obtain marketing approval and may affect our overall financial condition.

Current and future drug pricing legislative efforts may limit the prices for our products, if and when they are approved for marketing, which could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations included an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, was subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it would explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2026 by the Infrastructure Investment and Jobs Act.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The executive order directs the Department of Health and Human Services, or HHS, to create a plan within 45 days to combat “excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging.” On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, with passage of the IRA, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. We are continuing to analyze the impact of this law on our commercial strategy for avacincaptad pegol.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal drug pricing measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay

for pharmaceutical products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Outside the United States, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the U.S., reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the E.U. and the UK, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Reporting and payment obligations under Medicare Part B, the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to calculations, price reporting and payment obligations previously reported or paid. Such revisions could result in liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement. We expect that avacincaptad pegol, if approved for GA, would be reimbursed in large part by the "buy and bill" model under Medicare Part B, which requires that we report the average sale price, or ASP, for avacincaptad pegol, which will affect the level of reimbursement from Medicare. The determination of ASP can be complex and uncertain.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws or regulations related to calculations, price reporting or payments obligations, which increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations.

For example, the recently passed IRA has implications for programs such as Medicare Part D. Medicare Part D is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Individuals participating in a Medicare Part D prescription drug plan could experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and imposing price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, a company’s financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical company is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicare Part B, for covered outpatient drugs.

Additionally, if a pharmaceutical company overcharges the government in connection with the FSS program or Tricare Retail Pharmacy Program, whether due to a misstated federal ceiling price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against a company under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a

government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on a company's business, financial condition and results of operations.

If we enter into a collaboration for commercialization of our product candidates outside the United States, our collaborators would be subject to similar requirements outside of the U.S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes, which has caused average review times to fluctuate in recent years. Disruptions at the FDA and other agencies may slow the time for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last decade the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the COVID-19 pandemic, a number of companies in 2021 announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Following a period of false starts and temporary suspensions due to the Omicron variant, the FDA resumed domestic inspections in February 2022 and indicated that it would conduct foreign inspections beginning in April 2022 on a prioritized basis. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required, due to the ongoing COVID-19 pandemic and travel restrictions. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. In addition, many state licensing agencies underwent reductions in staff and office operations in wake of the COVID-19 pandemic and as a result, are taking longer to review and approve pharmaceutical licensing applications. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. International Travel Act of 1961, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We have relationships with certain officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations, including a number of public hospitals that are our clinical trial sites. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons or governmental programs, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In

certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

If we or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations at our laboratories and with our contracted manufacturing services involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our or our contractors' use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources and any coverage provided by our insurance. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We expect the Biden Administration to pass additional such laws and regulations. Some of those laws and regulations may govern the health and safety measures that employers must implement to protect their workers from the COVID-19 virus.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our product candidates or products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. There is also increasing focus from regulators and self-regulatory organizations on the environmental impact of operations and additional obligation on companies to make disclosures relating to them.

We and certain of our current and former board members and executive officers were named as defendants in lawsuits that could result in substantial costs and divert management's attention. We are in the process of settling those lawsuits, but the settlements are not yet final.

We and certain of our current and former executive officers were named as defendants in a purported consolidated putative class action lawsuit initiated in 2017 that generally alleges that we and certain of our officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the results of our Phase 2b trial and the prospects of our Phase 3 trials for our prior product candidate Fovista in combination with anti-VEGF agents for the treatment of wet AMD. Certain current and former members of our board of directors and current and former officers were also named as defendants in two shareholder derivative actions initiated in August 2018 (the Pacheco matter) and May 2021 respectively, which generally allege that the defendants breached their fiduciary duties to our company by failing to oversee our business during the period of the Phase 2b and Phase 3 clinical trials of Fovista. These complaints seek equitable and/or injunctive relief, unspecified damages, attorneys' fees, and other costs. On September 8, 2021, the parties in the class action executed a settlement agreement, which was finally approved by the court on September 16, 2022. In April 2022, our directors' and officers' liability insurance paid the full amount of the settlement, including plaintiff counsel's fees, directly to the plaintiffs' escrow account. The shareholder derivative actions were stayed while a special litigation committee of our board of directors, or the SLC, investigated the allegations contained in the complaints. On October 18, 2021, the parties notified the court overseeing the Pacheco matter that they had reached an agreement in principle to settle the action. On January 27, 2022, the parties executed a settlement agreement. On November 3, 2022, the court issued an order preliminarily approving the settlement. We do not expect this settlement, if granted final approval in its current form, to have a material impact on our financial condition. We are unable, however, to predict the outcome of the Pacheco matter at this time. Moreover, any conclusion of these matters in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance could have a material adverse effect on our financial condition and business. In addition, the litigation, including responding to discovery requests, caused our management and board of directors to divert time and attention to the litigation and could adversely impact our reputation, and if the litigation remains protracted, could further divert management and our board of directors' attention and resources from other priorities, including the execution of our business plan and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. Regardless of whether these lawsuits are

finally settled, additional lawsuits may be filed against us.

Risks Related to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove members of our board of directors and management.

Provisions in our certificate of incorporation and our by-laws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for stockholders.

Our stock price may be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general, and the market for smaller pharmaceutical and biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, including as a result of short selling by institutional and retail investors. As a result of this volatility, our stockholders may not be able to sell their shares of common stock at or above the price at which they purchased their shares. The market price for our common stock may be influenced by many factors, including:

- results of research, preclinical development activities and clinical trials for our product candidates, for example the increase in the trading of our common stock following our announcement of topline data from our GATHER2 trial;
- the timing and results of regulatory interactions and review for our product candidates;

- the success of products or technologies that compete with our product candidates, including results of clinical trials of product candidates of our competitors and of regulatory review of those product candidates, including the FDA's review of the NDA for Apellis's complement inhibitor and its expected PDUFA date;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- the level of expenses related to any of our product candidates or development programs;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the recruitment or departure of key personnel;
- the results of our efforts to in-license or acquire the rights to other product candidates and technologies for the treatment of retinal diseases, including additional sustained release delivery technologies for avacincaptad pegol;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- relevant scientific and medical developments;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as those caused by the COVID-19 pandemic or the ongoing military conflict in Ukraine;
- political, social, regulatory or legal developments in the United States and other countries; and
- the other factors described in this "Risk Factors" section.

In addition, the COVID-19 pandemic has caused significant disruptions in the financial markets, and may continue to cause such disruptions, and has also impacted, and may continue to impact, the volatility of our stock price and trading in our stock. Following periods of volatility in the market price of a company's stock, securities class-action litigation has often been instituted against that company. For example, we and certain of our current and former executive officers were named as defendants in a purported class action lawsuit and a related shareholder derivative action following our announcement in December 2016 of the initial, topline results from the first two of our Phase 3 Fovista trials for the treatment of wet AMD, which caused our stock price to decline significantly. See "*Risks Related to Our Business Plan, Financial Position and Need for Additional Capital—We and certain of our current and former executive officers were named as defendants in lawsuits that could result in substantial costs and divert management's attention. We are in the process of settling those lawsuits but the settlements are not yet final*." These proceedings and other similar litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, and cause additional volatility in the price of our common stock.

If a significant portion of our total outstanding shares are sold into the market, the market price of our common stock could drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. If the holders of a significant number of shares our common stock sell, or the market perceives that these holders will sell, the shares currently held by them, the price of our common stock may decline.

Moreover, we have filed, and expect to continue to file, registration statements on Form S-8 registering all shares of common stock that we may issue under our equity compensation plans. Once registered on Form S-8, shares underlying these equity awards can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

The ownership percentage of our stockholders may be diluted in the future, which could dilute the voting power or reduce the value of our outstanding shares of common stock.

As with any publicly traded company, the ownership percentage of our stockholders may be diluted in the future because of equity issuances for acquisitions, capital markets transactions, business development transactions or otherwise, including equity awards that we intend to continue to grant to our directors, officers and employees pursuant to our equity compensation plans. Our employees are also entitled, subject to certain conditions, to purchase our common stock at a discount pursuant to our Employee Stock Purchase Plan.

Also, our certificate of incorporation authorizes us to issue, without the approval of our shareholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock with respect to dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of our common stock.

For more information about the dilutive effects of financing or business development transactions we may undertake, see the risk factor above, "*Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates*."

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices, including potential environmental, social and governance (ESG) reporting.

As a public company, we incur and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish with our periodic Exchange Act reports a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we must document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources and engage outside consultants to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that our internal control over financial reporting may, in the future, be found to be ineffective under Section 404. Our identification of one or more material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

On March 21, 2022, the Securities and Exchange Commission proposed new rules relating to the disclosure of climate-related risks and disclosures. The SEC is currently reviewing comments to the proposed rule and a final rule is forthcoming. We are currently assessing the rule and its potential impact on our operations. To the extent this rule is finalized as proposed, we expect we would need to devote significant time and incur increased costs preparing for the disclosures required by this rule. In addition to the SEC's climate-related rule, many public companies are choosing or being required to report on their ESG goals, practices and risks.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth of our business. In addition, the terms of our Loan Agreement and any future debt agreements that we may enter into may preclude us from paying dividends without the lender's consent or at all. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

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

Stipulation of Settlement for Shareholder Derivative Action

As disclosed in “Note 8 — Commitments and Contingencies” in the notes to the financial statements filed with this Quarterly Report on Form 10-Q, on August 31, 2018, a shareholder derivative action was filed against current and former members of the Company's board of directors and certain current and former officers of the Company in the United States District Court for the Southern District of New York, captioned Luis Pacheco v. David R. Guyer, et al., Case No. 1:18-cv-07999. On January 27, 2022, the parties executed a settlement agreement (the “Stipulation of Settlement”) related to the shareholder derivative action. On November 3, 2022, the court issued an order preliminarily approving the settlement.

Copies of the Stipulation of Settlement and Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions are attached as Exhibits 99.1 and 99.2 to this Quarterly Report on Form 10-Q. The Company does not expect this settlement, if granted final approval in its current form, to have a material impact on its financial condition.

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 to Amendment No. 2 of the Registrant's Registration Statement on Form S-1 (File No. 333-190643) filed with the Securities and Exchange Commission on September 9, 2013)
10.1	+	Amendment No. 2 to Exclusive License Agreement with Know-How, by and among the Registrant, Trustees of the University of Pennsylvania and University of Florida Research Foundation, Incorporated, dated July 1, 2022
10.2		Loan and Security Agreement between the Registrant, IVERIC bio Gene Therapy LLC, Orion Ophthalmology LLC, each of the Registrant's other subsidiaries from time to time party thereto as a borrower, Hercules Capital, Inc. Silicon Valley Bank, and the several banks and other financial institutions or entities from time to time parties thereto, and Hercules Capital Inc., in its capacity as administrative agent and collateral agent for itself and the lenders, dated July 26, 2022 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 26, 2022)
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
99.1	*	Stipulation of Settlement and Notice of Pendency, dated January 20, 2023
99.2	*	Proposed Settlement of Shareholder Derivative Action, dated January 20, 2023
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 September 30, 2022 (unaudited) and December 31, 2021, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine month periods ended September 30, 2022 and 2021, (iii) Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine month periods ended September 30, 2022 and 2021, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine month periods ended September 30, 2022 and 2021 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: November 4, 2022

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

AMENDMENT NO. 2 TO EXCLUSIVE LICENSE AGREEMENT WITH KNOW-HOW

This Amendment No. 2 to Exclusive License Agreement with Know-How ("Amendment") is made effective as of July 1, 2022 by and among the Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("Penn"), the University of Florida Research Foundation, Incorporated, a nonstock, nonprofit Florida corporation ("UFRF"; together with Penn, the "Licensors") and IVERIC Bio Gene Therapy LLC, a Delaware limited liability company ("Licensee").

Recitals

WHEREAS, the Licensors and Licensee entered into an Exclusive License Agreement with Know-How, dated as of April 10, 2019, as amended by Amendment No. 1 on May 1, 2020 (the "License Agreement") pursuant to which the Licensors granted Licensee exclusive rights to certain patent rights and know-how and non-exclusive rights to certain know-how, in each case to develop, manufacture and commercialize certain gene therapy technologies in the field of treating diseases associated with mutations in the *BEST1* gene. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the License Agreement; and

WHEREAS, the parties now wish to amend the License Agreement by this Amendment;

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

1. **Payment.** Licensee hereby agrees to pay to Penn a non-creditable, non-refundable fee of [**] dollars ($[**]) within [**] following the execution of this Amendment.

2. **Section 3.2 First Commercial Sale – Milestones**. The first sentence of Section 3.2(a)(i) of the License Agreement is hereby deleted in its entirety and replaced with the following:

   "Licensee agrees that the First Commercial Sale of a [**] Product to a customer shall occur on or before [**]."

3. **Appendix F – Milestones**. Appendix F-1 is hereby deleted in its entirety and replaced with the following:
   Diligence Events for [**] **Products**

Diligence Event	Achievement Date
[**]	[**]
[**]	[**]
[**]	[**]

4. Except as expressly set forth in this Amendment, the License Agreement remains in full force and effect in accordance with its terms.

5. Licensors consent to Licensee filing a copy of this Amendment with the U.S. Securities and Exchange Commission, in accordance with its rules and regulations.

6. This Amendment may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) or electronic copy of this Amendment, including the signature pages, will be deemed an original.

[Signatures follow]

This Amendment No. 2 to Exclusive License Agreement with Know-How is entered into by the parties by their duly authorized signatories.

Licensors:

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ Benjamin Diblin
Name: Benjamin Dibling, Ph.D.
Title: Deputy Managing Director, Penn Center for Innovation

UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INCORPORATED

By: /s/ Jim O'Connell
Name: Jim O'Connell
Title: Director, UF Innovate | Tech Licensing

Licensee:

IVERIC BIO GENE THERAPY LLC

By: /s/ Keith Westby
Name: Keith Westby
Title: Chief Operating Officer

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 September 30, 2022 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: November 4, 2022

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 September 30, 2022 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: November 4, 2022

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 September 30, 2022 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: November 4, 2022

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 September 30, 2022 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: November 4, 2022

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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB STIPULATION OF SETTLEMENT

This Stipulation of Settlement, dated January 27, 2022 (the "Stipulation"), is made and entered into by and among the following Settling Parties,[1] by and through their respective counsel of record: (i) plaintiff Luis Pacheco ("Federal Plaintiff"), individually and derivatively on behalf of nominal defendant IVERIC bio, Inc. f/k/a/ Ophthotech Corporation ("Ophthotech" or the "Company"); (ii) Brian Ferber and Angel Ham, plaintiffs in the derivative action entitled *Ferber and Ham, Derivatively on Behalf of Ophthotech Corporation (Now Known As Iveric Bio, Inc.) v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup.) (the "State Plaintiffs"); (iii) stockholder Richard Waksman (the "Litigation Demand Stockholder") (the Federal Plaintiff, State Plaintiffs and

[1] All capitalized terms not otherwise defined are defined in section VI.1.

Litigation Demand Stockholder are collectively referred to herein as "Plaintiffs"); (iv) individual defendants David R. Guyer ("Guyer"), Glenn P. Sblendorio ("Sblendorio"), David E. Redlick ("Redlick"), Thomas Dyrberg ("Dyrberg"), Axel Bolte ("Bolte"), Michael J. Ross ("Ross"), Samir C. Patel ("Patel"), and Nicholas Galakatos ("Galakatos") (collectively, the "Individual Defendants"); and (v) nominal defendant Ophthotech (together with Individual Defendants, "Defendants").

This Stipulation is intended by the Settling Parties to fully, finally, and forever resolve, discharge, and settle the Released Claims, subject to the terms and conditions set forth herein.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Federal Derivative Action

1. Federal Plaintiff Commences This Derivative Litigation

On August 31, 2018, Federal Plaintiff filed a Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment (the "Complaint"), pleading derivative claims against the Individual Defendants on behalf of nominal defendant Ophthotech, captioned *Pacheco v. Guyer, et al*., C.A. No. 1:18-cv-07999-VSB (the "Federal Derivative Action").

Federal Plaintiff alleged that the Individual Defendants made and permitted the issuance of public statements that omitted material facts concerning (i) the average lesion size and average visual acuity of patients in the control group for the Phase 2b trial for the Company's lead drug candidate, Fovista, which allegedly had the effect of overstating the drug's efficacy; and (ii) changes made to the patient inclusion and exclusion criteria for the Fovista Phase 3 trials compared to the prior Phase 2b trial, which allegedly adversely impacted the potential for replicating the positive results of the Phase 2b trial. Federal Plaintiff further alleged that the Individual

Defendants' misstatements artificially inflated the Company's stock price, and that certain of the Individual Defendants sold their personally held shares of Ophthotech stock at those inflated prices.

Federal Plaintiff did not make a demand on Ophthotech's Board of Directors (the "Board") prior to filing suit and, instead, alleged that demand was excused as futile because there was reason to doubt (i) the disinterestedness of a majority of the Board members, based on the substantial threat of liability they faced; and (ii) the independence of a majority of the Board members, based on various business and financial entanglements.

2. The Court Denies the Defendants' Motion to Dismiss

On December 14, 2018, Defendants filed a Motion to Dismiss the Verified Stockholder Derivative Complaint (the "Motion to Dismiss") pursuant to Rule 23.1 of the Federal Rules of Civil Procedure, arguing that Federal Plaintiff had failed to adequately allege that a pre-suit demand on the Board would have been futile.

On February 22, 2019, Federal Plaintiff filed an opposition to the Motion to Dismiss, arguing that he had adequately alleged that demand on the Board would have been futile because, under Delaware law, the particularized facts alleged in the Complaint created reason to doubt the disinterestedness and/or independence of a majority of the Board members.

On April 3, 2019, Defendants filed their reply brief in support of their Motion to Dismiss.

On September 19, 2019, the Honorable Vernon S. Broderick denied the Motion to Dismiss.

The Individual Defendants and Ophthotech filed their answers to the Complaint on February 18, 2020.

3. The Board Appoints a Special Litigation Committee

In response to the denial of the Motion to Dismiss, on October 15, 2019, Ophthotech's Board passed a resolution establishing a Special Litigation Committee ("SLC"). Pursuant to the resolution of the Board, the SLC was "fully empowered to take and direct any and all actions on behalf of the Company with respect to [the Federal Derivative Action] and any stockholder derivative litigation [thereafter] filed that raises substantially similar allegations … or otherwise with respect to the allegations therein, including but not limited to investigating and making determinations concerning or related to claims and allegations of [the Federal Derivative Action], determining whether the pursuit of the [Federal Derivative Action] is in the Company's best interests, causing the Company to pursue claims, causing the Company to seek the dismissal of claims, and seeking any form of relief or action by the Court with respect to the [Federal Derivative Action]."

4. The Parties Agree to Terms on Discovery and a Temporary Stay

Following extensive negotiations, the parties agreed on terms for discovery and a temporary stay in order to permit the SLC to conduct its investigation.

Specifically, Defendants and the SLC, as appropriate and subject to the terms of the parties' stipulation, agreed to produce to Federal Plaintiff: (i) any final written SLC investigation report or presentation, if any, and any documents identified or referenced therein; (ii) in connection with such final report, if any, other SLC-related documents, including, *inter alia*, documents concerning the formation and independence of the SLC, minutes of relevant meetings of the Board and the SLC, and correspondence between SLC members and other members of the Board (hereinafter, the "SLC-related documents"); (iii) copies of all documents and written responses to discovery requests produced to the plaintiff in *Micholle v. Ophthotech Corporation, et al.*, C.A. No. 1:17-cv-

00210-VSB-GWG (the "Securities Action") in the form and manner in which such documents were produced to the Securities Action plaintiff; (iv) all written agreements regarding the scope of discovery to be produced by defendants in the Securities Action; and (v) all deposition transcripts generated in the Securities Action.

Federal Plaintiff expressly reserved all rights to seek to depose each member of the SLC regarding matters pertinent to the performance of their duties as members of the SLC, their independence, and the good faith, reasonableness, and independence of the SLC's investigation, deliberations and decision-making. Federal Plaintiff also expressly reserved all rights to propound formal requests for production, interrogatories and/or requests for admission regarding the independence of the SLC and whether the SLC conducted its investigation in good faith.

The parties to the Federal Derivative Action thereafter stipulated to and the Court ordered further stays (under the same or substantially similar terms) while the SLC continued its investigation.

5. Discovery and Information-Gathering

Between June 2020 and April 2021, Ophthotech produced to Federal Plaintiff more than 100,000 documents, constituting more than 4.2 million pages of material, which included transcripts of the depositions of percipient witnesses taken in the related Securities Action. Federal Plaintiff's Counsel attest that they used search terms and custodial information to identify and compile, and then reviewed and evaluated, critical non-public documents and deposition testimony produced by Ophthotech concerning the allegations underlying this litigation.

On April 27, 2021, Federal Plaintiff's Counsel participated in a meeting with Shearman & Sterling LLP, counsel for the SLC ("SLC Counsel"). Federal Plaintiff's Counsel, informed by their document review, made a presentation to SLC Counsel that addressed, among other things:

(i) the factual allegations, the legal theories for recovery, and the damages alleged to have been suffered by the Company; (ii) corporate governance and other changes that had been made at the Company since the commencement of the Federal Derivative Action; and (iii) potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing. Federal Plaintiff's Counsel and SLC Counsel also discussed the status of the SLC's investigation and next steps, including the possibility of engaging in mediation to explore a potential resolution of the matter.

B. The Litigation Demands

1. The Waksman Demand

On June 22, 2018, Waksman made a demand for the inspection of documents of Ophthotech under 8 Del. C. §220, seeking documents concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "220 Demand"). In response to the 220 Demand, Ophthotech and counsel for Waksman negotiated and entered into a confidentiality agreement. In late October 2018, Ophthotech provided approximately 2,200 pages of documents to Waksman and his counsel.

On January 23, 2019, subsequent to reviewing the documents, Waksman made a litigation demand on the Board, requesting that it take action to remedy breaches of fiduciary duties by the Individual Defendants in connection with alleged false and misleading statements concerning Fovista and insider selling by defendants Patel, Guyer, Galakatos, and Sblendorio (the "Waksman Demand"). On March 7, 2019, counsel for Waksman was informed that the Board had formed a demand review committee (the "Demand Review Committee"). Subsequent to the making of the Waksman Demand, counsel for Waksman kept in regular contact with counsel for the Demand

Review Committee and the SLC concerning the Board's investigations and (eventually) a potential settlement.

2. The Ferber/Ham Demand

On October 12, 2018, Ferber and Ham made a litigation demand upon the Board concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "Litigation Demand"). In response to the Litigation Demand, counsel for Ophthotech and counsel for Ferber and Ham exchanged correspondence. On November 30, 2018, counsel for the Company informed Ferber and Ham that the Board had formed the Demand Review Committee to examine the Litigation Demand. Later, that committee's membership was expanded to include Ophthotech director Adrienne Graves, and the SLC was appointed (as discussed above). Counsel for Ferber and Ham also requested that the Company obtain tolling agreements of the statute of limitations from the individual defendants named in this Litigation Demand. The Company executed tolling agreements with the individuals. Thereafter, counsel for Ferber and Ham requested action by the SLC and a production of documents as to the investigation. On March 6, 2021, Ferber and Ham filed an alleged demand-refused action in Supreme Court, New York County, captioned *Ferber, et al. v. Bolte, et al*., Index No. 154462/2021 (the "State Derivative Action").

Thereafter, counsel for Ferber and Ham and counsel for the Defendants agreed to enter into a temporary stay of the State Derivative Action while the parties pursued global settlement talks. In addition, Ferber and Ham and counsel for the Defendants entered into a stipulation in which the SLC agreed to produce to counsel for Ferber and Ham the SLC-related documents in accordance with the process provided for in connection with the Federal Derivative Action.

II. SETTLEMENT EFFORTS

A mediation was set for June 21, 2021, with the Honorable Layn R. Phillips (Fmr.) and Niki Mendoza of Phillips ADR (the "Mediator"), both of whom are nationally recognized mediators with extensive experience mediating complex stockholder disputes similar to the Derivative Actions.

In advance of the mediation, Plaintiffs sent Defendants settlement demand letters, which demanded, *inter alia*, a suite of corporate governance measures designed to prevent a recurrence of the alleged wrongdoing at the heart of this litigation.

On June 21, 2021, the Settling Parties and the SLC participated in an all-day mediation session with the Mediator. The Settling Parties and the SLC made substantial progress at the mediation but were unable to resolve the Derivative Actions that day.

Over the course of the next month, the parties continued to engage in arm's-length negotiations regarding the terms of a potential settlement, including, in particular, corporate governance measures at the Company that could form the basis for a settlement. These post-mediation negotiations were conducted via written and telephonic communications, with the continued oversight of the Mediator. The Settling Parties ultimately reached an agreement in principle on the material substantive terms of the Settlement, including the Corporate Governance Measures.

Thereafter, with the substantial involvement of the Mediator, the Settling Parties commenced negotiations regarding the attorneys' fees and expenses to be paid to Plaintiffs' Counsel. Despite their good faith efforts, the Settling Parties were unable to reach an agreement on an appropriate amount of attorneys' fees on their own. Accordingly, on September 1, 2021, the Mediator issued a mediator's recommendation for attorneys' fees and expenses in the amount of

$2,450,000, to be paid to Plaintiffs' Counsel by the Individual Defendants' insurer(s) (the "Fee and Expense Amount," as defined below). The Settling Parties agreed to the mediator's recommendation regarding the Fee and Expense Amount on September 3, 2021.

The Stipulation, together with the exhibits thereto, reflects the final and binding agreement between the Settling Parties.

III. PLAINTIFFS' CLAIMS AND THE BENEFITS OF SETTLEMENT

Plaintiffs believe that the Derivative Actions have substantial merit, and Plaintiffs' entry into this Stipulation and Settlement is not intended to be and shall not be construed as an admission or concession concerning the relative strength or merit of the claims alleged in the Derivative Actions. However, Plaintiffs and Plaintiffs' Counsel recognize and acknowledge the significant risk, expense, and length of continued proceedings necessary to prosecute the Derivative Actions against the Individual Defendants through trial and possible appeals. Plaintiffs' Counsel also have taken into account the uncertain outcome and the risk of any litigation, especially in complex cases such as the Derivative Actions, as well as the difficulties and delays inherent in such litigation. Plaintiffs' Counsel are also mindful of the inherent problems of prevailing in the face of a potential motion to terminate by the SLC that was appointed by the Board here, the possible defenses to the claims brought in the Derivative Actions, and the difficulty of prevailing at trial in shareholder derivative litigation, generally.

Plaintiffs' Counsel have conducted extensive investigation and analysis, including, *inter alia*: (i) reviewing the voluminous non-public documents produced in the course of this litigation, including the discovery generated in the related Securities Action and produced to Federal Plaintiff; (ii) reviewing Ophthotech's press releases, public statements, U.S. Securities and Exchange Commission ("SEC") filings, and securities analysts' reports and advisories about the

Company; (iii) reviewing related media reports about the Company; (iv) researching applicable law with respect to the claims alleged in the Derivative Actions and potential defenses thereto; (v) preparing and filing derivative complaints; (vi) preparing and sending inspection and litigation demands; (vii) conducting damages analyses; (viii) evaluating the merits of, and the defendants' potential liability in connection with, the Securities Action; (ix) participating in a formal meeting and making a presentation to SLC Counsel regarding the factual allegations, the legal theories for recovery, the damages alleged to have been suffered by the Company, corporate governance and other changes that had been made at the Company, and potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing; (x) reviewing the Company's existing corporate governance policies and preparing comprehensive yet targeted settlement demands detailing proposed corporate governance measures to strengthen the Company's governance; (xi) participating in extensive settlement discussions, including an all-day mediation and continued follow-up communications with SLC Counsel and Defendants' Counsel and the Mediator; and (xii) negotiating this Stipulation and the exhibits hereto.

Based on Plaintiffs' Counsel's thorough review and analysis of the relevant facts, allegations, defenses, and controlling legal principles, Plaintiffs' Counsel believe that the Settlement set forth in this Stipulation is fair, reasonable, and adequate, and confers substantial benefits upon Ophthotech. Based upon Plaintiffs' Counsel's evaluation, Plaintiffs have determined that the Settlement is in the best interests of Ophthotech and have agreed to settle the Derivative Actions upon the terms and subject to the conditions set forth herein.

IV. DEFENDANTS' DENIALS OF WRONGDOING AND LIABILITY

Defendants have denied and continue to deny each and all of the claims and contentions alleged by Plaintiffs in the Derivative Actions, and the Individual Defendants have expressly

denied and continue to deny all charges of wrongdoing or liability against them arising out of any of the conduct, statements, acts, or omissions alleged, or that could have been alleged, in the Derivative Actions. Defendants have also taken into account the uncertainty and risks inherent in any litigation, especially in complex cases like the Derivative Actions. Defendants have, therefore, determined that it is in the best interests of Ophthotech for the Derivative Actions to be settled in the manner and upon the terms and conditions set forth in this Stipulation.

Neither this Stipulation, nor any of its terms or provisions, nor entry of the Judgment, nor any document or exhibit referenced by or attached to this Stipulation, nor any action taken to carry out this Stipulation, is, may be construed as, or may be used as evidence of the validity of any of the Released Claims or as an admission by or against the Individual Defendants of any fault, wrongdoing, or concession of liability whatsoever.

V. INDEPENDENT DIRECTOR APPROVAL

The members of the SLC, acting on behalf of the Company, have unanimously approved a resolution reflecting their determination, in an exercise of their business judgment, that: (a) Plaintiffs' litigation and settlement efforts in the Derivative Actions were a material and contributing factor in the Board's agreement to adopt, implement, and maintain the Corporate Governance Measures for the agreed term; (b) the Corporate Governance Measures reflected in **Exhibit A** attached hereto confer substantial benefits on the Company and its stockholders; and (c) the Settlement is fair, reasonable and in the best interests of the Company and its stockholders.

VI. TERMS OF STIPULATION AND AGREEMENT OF SETTLEMENT

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED by and among the undersigned counsel for the Settling Parties herein, in consideration of the benefits flowing to the parties from the Settlement, and subject to the approval of the Court, that the claims asserted in

the Derivative Actions and the Released Claims shall be finally and fully compromised, settled, and released, and the Derivative Actions shall be dismissed with prejudice and with full preclusive effect as to all Settling Parties, upon and subject to the terms and conditions of this Stipulation, as set forth below.

1. Definitions

As used in this Stipulation, the following terms have the meanings specified below:

1.1 "Change in Control Event" means:

a. the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination and (y) no individual, entity or group beneficially owns, directly or indirectly, 50% or more of the combined voting power of the then-outstanding securities of such corporation

entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

b. the liquidation or dissolution of the Company.

1.2 "Corporate Governance Measures" means the corporate governance measures as set forth in **Exhibit A** attached hereto.

1.3 "Court" means the U.S. District Court for the Southern District of New York.

1.4 "Current Company Stockholders" means any Person who owned Ophthotech common stock as of the date of the execution of this Stipulation and continues to hold Ophthotech common stock as of the date of Settlement Hearing, excluding the Individual Defendants, the officers and directors of Ophthotech, members of their immediate families, and their legal representatives, heirs, successors, or assigns, and any entity in which Individual Defendants have or had a controlling interest.

1.5 "Defendants" means, collectively, nominal defendant Ophthotech and the Individual Defendants.

1.6 "Defendants' Counsel" means Wilmer Cutler Pickering Hale and Dorr LLP and Morgan, Lewis & Bockius LLP or their successors, and any other law firm that appeared for Defendants in any of the Derivative Actions.

1.7 "Derivative Actions" means the following matters, including, without limitation, all related stockholder demands: (a) *Pacheco v. Guyer, et al.*, Case No. 1:18-cv-07999-VSB (S.D.N.Y.); (b) *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup. Ct. N.Y. Cnty.); and (c) the litigation demand made by Richard Waksman, dated January 23, 2019.

1.8 "Effective Date" means the date by which the events and conditions specified in paragraph 6.1 of this Stipulation have been met and have occurred.

1.9 "Federal Derivative Action" means *Pacheco v. Guyer, et al.*, Case No. 1:18-cv-07999-VSB (S.D.N.Y.).

1.10 "Federal Plaintiff" means Luis Pacheco.

1.11 "Federal Plaintiff's Counsel" means Robbins LLP and The Law Offices of Thomas G. Amon.

1.12 "Fee and Expense Amount" shall have the meaning defined in paragraph 4.2 hereof.

1.13 "Final" means the date upon which the last of the following shall occur with respect to the Judgment approving this Stipulation, substantially in the form of **Exhibit C** attached hereto: (1) the expiration of the time to file a notice of appeal from the Judgment; or (2) if an appeal has been filed, the court of appeals has either affirmed the Judgment or dismissed that appeal and the time for any reconsideration or further appellate review has passed; or (3) if a higher court has granted further appellate review, that court has either affirmed the underlying Judgment or affirmed the court of appeal's decision affirming the Judgment or dismissing the appeal. For purposes of this paragraph, an "appeal" shall not include any appeal that concerns only the issue of attorneys' fees and expenses or the payment of a service award. Any proceeding or order, or any appeal or petition for a writ of certiorari pertaining solely to the application for attorneys' fees, costs, or expenses, shall not in any way delay or preclude the Judgment from becoming Final.

1.14 "Individual Defendants" means David R. Guyer, Glenn P. Sblendorio, David E. Redlick, Thomas Dyrberg, Axel Bolte, Michael J. Ross, Samir C. Patel, and Nicholas Galakatos.

1.15 "Judgment" means the Order and Final Judgment to be rendered by the Court, substantially in the form attached hereto as **Exhibit C**.

1.16 "Mediator" means Phillips ADR Enterprises.

1.17 "Notice" means the Notice of Proposed Settlement and of Settlement Hearing, substantially in the form attached hereto as **Exhibit B-1**.

1.18 "Person" or "Persons" means an individual, corporation, limited liability corporation, professional corporation, partnership, limited partnership, limited liability partnership, association, joint stock company, estate, legal representative, trust, unincorporated association, government or any political subdivision or agency thereof and any business or legal entity and their spouses, heirs, predecessors, successors, representatives, or assignees.

1.19 "Plaintiffs" means Luis Pacheco, Richard Waksman, Brian Ferber, and Angel Ham.

1.20 "Plaintiffs' Counsel" means Robbins LLP, The Law Offices of Thomas G. Amon, Gainey McKenna & Egleston, Hynes & Hernandez LLC, Bragar Eagel & Squire, P.C., and any other law firm that appeared for Plaintiffs in any of the Derivative Actions.

1.21 "Ophthotech" or the "Company" means nominal defendant IVERIC bio, Inc. f/k/a/ Ophthotech Corporation, a Delaware corporation, and its affiliates, subsidiaries, predecessors, successors, and assigns.

1.22 "Related Persons" means: (i) with regard to each Individual Defendant, the Individual Defendants' spouses, marital communities, immediate family members, heirs,

executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns or any other entity in which any Individual Defendant has a controlling interest, and each and all of their respective past and present officers, directors, employees, agents, affiliates, parents, subsidiaries, divisions, attorneys, accountants, auditors, advisors, insurers, co-insurers, re-insurers, heirs, executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns; and (ii) with regard to Ophthotech, all past or present agents, officers, directors, attorneys, accountants, auditors, advisors, insurers, co-insurers, reinsurers, partners, controlling shareholders, joint venturers, related or affiliated entities, advisors, employees, affiliates, predecessors, successors, parents, subsidiaries, insurers, and assigns for Ophthotech.

1.23 "Released Claims" means any and all manner of claims, demands, rights, liabilities, losses, obligations, duties, damages, costs, debts, expenses, interest, penalties, sanctions, fees, attorneys' fees, actions, potential actions, causes of action, suits, agreements, judgments, decrees, matters, issues and controversies of any kind, nature or description whatsoever, whether known or unknown, disclosed or undisclosed, accrued or unaccrued, apparent or not apparent, foreseen or unforeseen, matured or not matured, suspected or unsuspected, liquidated or not liquidated, fixed or contingent, including without limitation Unknown Claims (as defined in paragraph 1.33 below), whether based on state, local, foreign, federal, statutory, regulatory, common or other law or rule, brought or that could be brought by Ophthotech or derivatively on behalf of Ophthotech that arise out of or relate to: (i) the allegations asserted in the Derivative Actions; or (ii) the Settlement, except for any claims to enforce the Settlement. Excluded from the term "Released Claims" are all claims asserted in the Securities Action.

1.24 "Released Persons" means collectively, Ophthotech, the Individual Defendants, and their Related Persons. "Released Person" means, individually, any of the Released Persons.

1.25 "Releasing Parties" means Plaintiffs, all other Current Company Stockholders, Plaintiffs' Counsel, and Ophthotech. "Releasing Party" means, individually, any of the Releasing Parties.

1.26 "Securities Action" means the securities class action styled as *Micholle v. Ophthotech Corp, et al.*, No. 1:17-cv-00210-VSB-GWG.

1.27 "Settlement" means the settlement and compromise of the Derivative Actions as provided for herein.

1.28 "Settlement Hearing" means the hearing or hearings at which the Court will review the adequacy, fairness, and reasonableness of the Settlement.

1.29 "Settling Parties" means, collectively, Plaintiffs and Defendants. "Settling Party" means, individually, any of the Settling Parties.

1.30 "State Derivative Action" means *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup. Ct. N.Y. Cnty.).

1.31 "State Plaintiffs" means Brian Ferber and Angel Ham.

1.32 "Summary Notice" means the Summary Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions, substantially in the form attached hereto as **Exhibit B-2**.

1.33 "Unknown Claims" means any Released Claim(s) which Plaintiffs or Defendants do not know of or suspect to exist in his, her, or its favor at the time of the release of the Released Persons. With respect to any and all Released Claims, the Settling Parties agree that

upon the Effective Date, the Settling Parties expressly waive the provisions, rights and benefits conferred by or under California Civil Code section 1542, or any other law of the United States or any state or territory of the United States, or principle of common law, which is similar, comparable, or equivalent to section 1542, which provides:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

The Settling Parties acknowledge that they may hereafter discover facts in addition to or different from those now known or believed to be true by them, with respect to the subject matter of the Released Claims, but it is the intention of the Settling Parties to completely, fully, finally, and forever compromise, settle, release, discharge, and extinguish any and all Released Claims, known or unknown, suspected or unsuspected, contingent or absolute, accrued or unaccrued, apparent or unapparent, which do now exist, or heretofore existed, or may hereafter exist, and without regard to the subsequent discovery of additional or different facts. The Settling Parties acknowledge that the foregoing waivers were separately bargained for and are key elements of this Stipulation of which this release is a part.

2. Terms of the Settlement

2.1 As a result of the filing, prosecution, and settlement of the Derivative Actions, the Company shall, within sixty (60) days following final settlement approval, adopt and implement the Corporate Governance Measures as set forth in **Exhibit A**.

2.2 Subject to Paragraph 2.3, and except as otherwise provided herein, the Corporate Governance Measures shall remain in effect for a period of no less than four (4) years following final settlement approval. The Corporate Governance Measures may be amended or eliminated if

a majority of the independent members of the Board determine in a good faith exercise of their business judgment that the implementation or maintenance of the Corporate Governance Measure(s) would be contrary to applicable laws or regulations, including the Board's fiduciary duties. In such event, the independent directors, to the extent their fiduciary obligations allow based upon their good faith exercise of business judgment, shall adopt an amended or substitute measure that addresses the same goals, purposes and/or functions of the original Corporate Governance Measure(s) as soon as practicable. Any changes made pursuant to the foregoing two sentences shall be published in the Company's next regular quarterly filing with the SEC. For the sake of clarity, nothing in this Stipulation or Settlement precludes the Board in its good faith exercise of business judgment from implementing amendments or modifications to provisions of the policies and procedures addressed by the Corporate Governance Measures to the extent such amendments or modifications do not conflict with changes to such policies and procedures specifically implemented by the Corporate Governance Measures.

2.3 Upon the occurrence of any Change in Control Event, all duties and obligations created by Paragraph 2.2 shall become subject to the good faith exercise of the succeeding board's or controlling group's or entity's business judgment. Defendants represent that they are not aware of any actual or potential forthcoming Change in Control Event.

2.4 The Company acknowledges that the members of the SLC have unanimously approved a resolution reflecting their determination, in an exercise of their business judgment, that: (a) Plaintiffs' litigation and settlement efforts in the Derivative Actions were a material and contributing factor in the Board's agreement to adopt, implement, and maintain the Corporate Governance Measures for the agreed term; (b) the Corporate Governance Measures confer

substantial benefits on the Company and its stockholders; and (c) the Settlement is fair, reasonable and in the best interests of the Company and its stockholders.

3. Approval and Notice

3.1 Promptly after execution of this Stipulation, the Settling Parties shall submit this Stipulation together with its exhibits to the Court and shall jointly apply for entry of an order (the "Preliminary Approval Order"), substantially in the form of **Exhibit B** attached hereto, requesting: (i) preliminary approval of the Settlement set forth in this Stipulation; (ii) approval of the form and manner of providing notice of the Settlement to Current Company Stockholders; and (iii) a date for the Settlement Hearing.

3.2 Notice to Current Company Stockholders shall consist of a Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions ("Notice"), which includes the general terms of the Settlement set forth in this Stipulation and the date of the Settlement Hearing, substantially in the form attached hereto as **Exhibit B-1**, as well as a Summary Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions ("Summary Notice"), substantially in the form attached hereto as **Exhibit B-2**.

3.3 The Company shall undertake the administrative responsibility for giving notice to Current Company Stockholders and shall be solely responsible for paying the costs and expenses related to providing such notice to its stockholders as follows: Within ten (10) business days after the entry of the Preliminary Approval Order, the Company shall cause the Stipulation of Settlement and Notice to be filed with the SEC along with an SEC Form 8-K or other appropriate filing, and the Company shall publish the Summary Notice one time in the national edition of *Investors' Business Daily*. The Company shall also publish the Stipulation of Settlement and Notice on an Internet page that the Company shall create for this purpose, which shall be accessible via a link

on the "Investors" page of the Company's website through the date of the Settlement Hearing, the address of which shall be contained in the Notice and Summary Notice. If additional notice is required by the Court, then the cost and administration of such additional notice will be borne by the Company. The Settling Parties believe the content and manner of the notice, as set forth in this paragraph, constitutes adequate and reasonable notice to Current Company Stockholders pursuant to applicable law and due process. Prior to the Settlement Hearing, Defendants' Counsel shall file with the Court an appropriate affidavit or declaration with respect to filing and posting the Notice and Summary Notice.

3.4 Pending the Court's determination as to final approval of the Settlement, Plaintiffs and all Current Company Stockholders are barred and enjoined from commencing, instituting, filing, intervening in, participating in, receiving any benefit from, or prosecuting any action, including without limitation any derivative action, asserting any of the Released Claims against any of the Released Persons.

4. Attorneys' Fees and Reimbursement of Expenses

4.1 After negotiating the principal terms of the Settlement, counsel for the Settling Parties, the SLC and Defendants' insurers, acting by and through their respective counsel, and with the substantial assistance of the Mediator, separately negotiated the attorneys' fees and expenses the Individual Defendants would cause their insurers to pay to Plaintiffs' Counsel based on the substantial benefits conferred upon Ophthotech by the Settlement.

4.2 In consideration of the substantial benefits conferred upon Ophthotech as a direct result of the Settlement and the efforts of Plaintiffs and Plaintiffs' Counsel in the Derivative Actions, and subject to Paragraph 4.3 of this Stipulation, the Individual Defendants shall cause their insurers to pay Plaintiffs' Counsel attorneys' fees and expenses in the total amount of

$2,450,000, or such other amount as may be awarded by the Court not to exceed $2,450,000 (the "Fee and Expense Amount"). The members of the SLC, in the good faith exercise of their business judgment, have approved the agreed-to Fee and Expense Amount in light of the substantial benefits conferred upon Ophthotech as a result of the Settlement and Plaintiffs' Counsel's efforts in this litigation.

4.3 Defendants shall cause the Fee and Expense Amount to be paid into an account controlled by Federal Plaintiffs' Counsel within thirty (30) calendar days after the later of the entry of (a) an order from the Court preliminarily approving the settlement, or (b) the provision to Defendants of all information necessary to effectuate a transfer of funds to the account controlled by Federal Plaintiffs' Counsel, including the bank name and ABA routing number, address, account name and number, and a signed W-9 reflecting the taxpayer identification number for Federal Plaintiffs' Counsel, notwithstanding the existence of any timely filed objections thereto, or potential for appeal therefrom, or collateral attack on the Settlement or any part thereof. Plaintiffs' Counsel shall be severally obligated to make refunds or repayment of such applicable amount received directly to the funding insurers if any specified condition to the Settlement is not satisfied or, as a result of any appeal and/or further proceedings on remand, or successful collateral attack, the Court's approval of the Settlement is reversed, or the Fee and Expense Amount is reduced or reversed, or the Effective Date for any reason does not occur. In the event that the Judgment fails to become Final as defined in paragraph 1.13 herein, then Plaintiffs' Counsel shall be severally obligated to make appropriate refunds or repayments to the Defendants' insurers of any attorneys' fees and expenses previously paid within fifteen (15) business days from receiving notice from Defendants' Counsel of written payment instructions and tax information.

4.4 The Fee and Expense Amount shall constitute final and complete payment for Plaintiffs' Counsel's attorneys' fees and expenses that have been incurred or will be incurred in connection with the Derivative Actions. Plaintiffs' Counsel shall allocate the Fee and Expense Amount among themselves. Plaintiffs' Counsel agree that any disputes regarding the allocation of the Fee and Expense Amount among them shall be presented to and be mediated, and, if necessary, finally decided and resolved, by the Mediator on the terms and subject to the processes and procedures set forth by the Mediator. The Mediator's fees and costs for any such mediation and/or arbitration shall be borne solely by Plaintiffs' Counsel and allocated among Plaintiffs' Counsel by agreement or as finally determined by the Mediator. Defendants shall have no responsibility for, and no liability with respect to, the allocation of the attorneys' fees awarded among Plaintiffs' Counsel and/or to any other person who may assert some claim thereto. Any dispute regarding any allocation of fees or expenses among Plaintiffs' Counsel shall have no effect on the Settlement.

4.5 The Settling Parties further stipulate that Plaintiffs' Counsel may apply to the Court for service awards of up to $5,000 for each of the Plaintiffs in recognition of Plaintiffs' participation and efforts in the prosecution of the Derivative Actions, to be paid from Plaintiffs' Counsel's Fee and Expense Amount only upon approval of the Court. The failure of the Court to approve any requested service award, in whole or in part, shall have no effect on the Settlement set forth in this Stipulation. Neither Ophthotech nor any of the Individual Defendants shall be liable for any portion of any service award.

5. Releases

5.1 The State Derivative Action shall be voluntarily dismissed by the State Plaintiffs with prejudice within seven (7) calendar days after the Effective Date.

5.2 Upon the Effective Date, the Releasing Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged with prejudice and on the merits, to the fullest extent permitted by law, each and all of the Released Persons from and with respect to each and all of the Released Claims (including Unknown Claims), and will be forever barred and enjoined from commencing, instituting, or prosecuting any action or proceeding, in any forum, asserting any of the Released Claims against any of the Released Persons, including but not limited to any and all claims arising out of, relating to, or in connection with the defense, settlement, or resolution of the Derivative Actions against the Released Persons. The obligations incurred pursuant to this Stipulation shall be in full and final disposition of the Derivative Actions and each of the Released Claims. It is the intention of the Settling Parties that the Settlement eliminate all further risk and liability relating to the Released Claims, and that the Settlement shall be a final and complete resolution of all claims asserted or which could be or could have been asserted with respect to the Released Claims against any of the Released Persons. Nothing herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of this Stipulation.

5.3 Upon the Effective Date, each of the Defendants shall be deemed to have fully, finally, and forever released, relinquished, and discharged Plaintiffs and Plaintiffs' Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection with the institution, prosecution, assertion, settlement, or resolution of the Derivative Actions or the Released Claims. Nothing herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of this Stipulation.

5.4 Upon the Effective Date, each of the Settling Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged the members of the SLC and SLC Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection

with the investigation, settlement, or resolution of the Derivative Actions or the Released Claims. Nothing herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of this Stipulation.

6. Conditions of Settlement; Effect of Disapproval, Cancellation, or Termination

6.1 The Effective Date of this Stipulation shall be the first date after and conditioned on the occurrence of all of the following events:

a. Board approval of the Settlement, which Ophthotech represents has already been accomplished;

b. Court preliminary approval of the Settlement and approval of the content and method of providing Notice of the proposed Settlement to Current Company Stockholders, and the subsequent dissemination of the Notice to Current Company Stockholders as provided herein;

c. Court entry of the Judgment, in all material respects in the form set forth as **Exhibit C** annexed hereto, approving the Settlement and dismissing the Federal Derivative Action with prejudice, without awarding costs to any party, except as provided herein;

d. payment of the Fee and Expense Amount in accordance with paragraphs 4.1-4.5; and

e. the passing of the date upon which the Judgment becomes Final.

6.2 If any of the conditions specified above in paragraph 6.1 are not met, then this Stipulation shall be canceled and terminated subject to paragraph 6.3, unless counsel for the Settling Parties mutually agree in writing to proceed with this Stipulation.

6.3 If for any reason the Effective Date of this Stipulation does not occur, or if this Stipulation is in any way canceled, terminated or fails to become Final in accordance with its

terms: (a) all Settling Parties and Released Persons shall be restored to their respective positions in the Derivative Actions as of January 27, 2022; (b) all releases delivered in connection with this Stipulation shall be null and void, except as otherwise provided for in this Stipulation; (c) the Fee and Expense Amount paid to Plaintiffs' Counsel shall be refunded and returned within thirty (30) calendar days; and (d) all negotiations, proceedings, documents prepared, and statements made in connection herewith shall be without prejudice to the Settling Parties, shall not be deemed or construed to be an admission by a Settling Party of any act, matter, or proposition, and shall not be used in any manner for any purpose in any subsequent proceeding in the Derivative Actions or in any other actions or proceedings. In such event, the terms and provisions of this Stipulation shall have no further force and effect with respect to the Settling Parties and shall not be used in the Derivative Actions or in any other proceedings for any purpose.

7. Miscellaneous Provisions

7.1 The Settling Parties: (a) acknowledge that it is their intent to consummate this Stipulation; and (b) agree to act in good faith and cooperate to take all reasonable and necessary steps to expeditiously implement the terms and conditions of this Stipulation.

7.2 In the event that any part of the Settlement is found to be unlawful, void, unconscionable, or against public policy by a court of competent jurisdiction, the remaining terms and conditions of the Settlement shall remain intact.

7.3 The Settling Parties intend this Settlement to be a final and complete resolution of all disputes between them with respect to the Derivative Actions. The Settlement compromises claims that are contested and shall not be deemed an admission by any Settling Party as to the merits of any claim, allegation, or defense. The Settling Parties and their respective counsel agree that at all times during the course of the litigation, each has complied with the requirements of the

applicable laws and rules of the Court, including, without limitation, Rule 11 of the Federal Rules of Civil Procedure and all other similar laws and/or rules governing professional conduct.

7.4 Each of the Individual Defendants expressly denies and continues to deny all allegations of wrongdoing or liability against himself or herself arising out of any conduct, statements, acts, or omissions alleged, or which could have been alleged, in the Derivative Actions. The existence of the provisions contained in this Stipulation shall not be deemed to prejudice in any way the respective positions of the Settling Parties with respect to the Derivative Actions, shall not be deemed a presumption, a concession, or admission by any of the Settling Parties of any fault, liability, or wrongdoing as to any facts, claims, or defenses that have been or might have been alleged or asserted in the Derivative Actions or with respect to any of the claims settled in the Derivative Actions, or any other actions or proceeding, and shall not be interpreted, construed, deemed, invoked, offered, or received in evidence or otherwise used by any person in the Derivative Actions, or in any other actions or proceeding, except for any litigation or judicial proceeding arising out of or relating to this Stipulation or the Settlement whether civil, criminal, or administrative, for any purpose other than as provided expressly herein.

7.5 This Stipulation may be modified or amended only by a writing signed by the signatories hereto.

7.6 This Stipulation shall be deemed drafted equally by all Settling Parties.

7.7 No representations, warranties, or inducements have been made to any of the Settling Parties concerning this Stipulation or its exhibits other than the representations, warranties, and covenants contained and memorialized in such documents.

7.8 Each counsel or other Person executing this Stipulation or its exhibits on behalf of any of the Settling Parties hereby warrants that such Person has the full authority to do so.

7.9 The exhibits to this Stipulation are material and integral parts hereof and are fully incorporated herein by this reference.

7.10 This Stipulation and the exhibits attached hereto constitute the entire agreement among the Settling Parties with respect to the subject matter hereof and supersede all prior and contemporaneous oral and written agreements and discussions.

7.11 In the event that there exists a conflict or inconsistency between the terms of this Stipulation and the terms of any exhibit hereto, the terms of this Stipulation shall prevail.

7.12 This Stipulation may be executed in one or more counterparts, including by signature transmitted by facsimile, e-mailed PDF files, or DocuSign. Each counterpart, when so executed, shall be deemed to be an original, and all such counterparts together shall constitute the same instrument.

7.13 This Stipulation shall be considered to have been negotiated, executed and delivered, and to be wholly performed, in the State of New York, and the rights and obligations of the parties to this Stipulation shall be construed and enforced in accordance with, and governed by, the internal, substantive laws of the State of New York without giving effect to that State's choice of law principles.

7.14 Except as otherwise provided herein or in the Court's Preliminary Approval Order or Final Approval Order, the Settling Parties agree that any disputes between or amongst the Settling Parties related to the interpretation of any of the Settlement terms shall be presented to and be mediated, and, if necessary, finally decided and resolved by the Mediator on the terms and subject to the processes and procedures set forth by the Mediator.

7.15 The Court shall retain jurisdiction to implement and enforce the terms of the Stipulation and the Court's Final Approval Order, and the Settling Parties submit to the jurisdiction

of the Court for purposes of implementing and enforcing the Settlement embodied in the Stipulation and Final Approval Order.

IN WITNESS WHEREOF, the Settling Parties have caused this Stipulation to be executed by their duly authorized attorneys.

Dated: January 27, 2022

ROBBINS LLP

SHANE P. SANDERS
BRIAN J. ROBBINS
CRAIG W. SMITH
5040 Shoreham Place
San Diego, CA 92122
Telephone: (619) 525-3990
Facsimile: (619) 525-3991
E-mail: brobbins@robbinsllp.com
csmith@robbinsllp.com
ssanders@robbinsllp.com

LAW OFFICES OF THOMAS G. AMON
THOMAS G. AMON
420 Lexington Avenue, Suite 1402
New York, NY 10170
Telephone: (212) 810-2430
E-mail: tamon@amonlaw.com

Counsel for Federal Plaintiff Luis Pacheco

Dated: January 27, 2022

GAINEY McKENNA & EGLESTON

THOMAS J. MCKENNA
GREGORY M. EGLESTON
501 Fifth Avenue, 19th Floor
New York, NY 10017
Telephone: (212) 983-1300
Facsimile: (212) 983-0383
E-mail: tjmckenna@gme-law.com
gegleston@gme-law.com

Counsel for State Plaintiffs Brian Ferber and

Angel Ham

Dated: January 27, 2022

HYNES & HERNANDEZ, LLC

MICHAEL J. HYNES
LIGAYA T. HERNANDEZ
101 Lindenwood Drive, Suite 225
Malvern, PA 19355
Telephone: (484) 875-3116

Counsel for Litigation Demand Shareholder Richard Waksman

Dated: January 27, 2022

WILMER CUTLER PICKERING
HALE AND DORR LLP

MICHAEL G. BONGIORNO
JEREMY T. ADLER
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Telephone: (212) 230-8800
Facsimile: (212) 230-8888
E-mail: michael.bongiorno@wilmerhale.com
jeremy.adler@wilmerhale.com

Counsel for Defendants and Nominal Defendant

JORDAN D. HERSHMAN
MORGAN, LEWIS & BOCKIUS LLP
One Federal St. Boston, MA 02110
Telephone: (617) 951-8455
Facsimile: (617) 345-5037
E-mail: jordan.hershman@morganlewis.com

Counsel for Defendants David R. Guyer and Samir C. Patel

Angel Ham

Dated: January 27, 2022

HYNES & HERNANDEZ, LLC

MICHAEL J. HYNES
LIGAYA T. HERNANDEZ
101 Lindenwood Drive, Suite 225
Malvern, PA 19355
Telephone: (484) 875-3116

Counsel for Litigation Demand Shareholder Richard Waksman

Dated: January 27, 2022

WILMER CUTLER PICKERING
HALE AND DORR LLP

Michael Bongiorno / JTA

MICHAEL G. BONGIORNO
JEREMY T. ADLER
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Telephone: (212) 230-8800
Facsimile: (212) 230-8888
E-mail: michael.bongiorno@wilmerhale.com
jeremy.adler@wilmerhale.com

Counsel for Defendants and Nominal Defendant

JORDAN D. HERSHMAN
MORGAN, LEWIS & BOCKIUS LLP
One Federal St. Boston, MA 02110
Telephone: (617) 951-8455
Facsimile: (617) 345-5037
E-mail: jordan.hershman@morganlewis.com

Counsel for Defendants David R. Guyer and Samir C. Patel

EXHIBIT A

EXHIBIT A

CORPORATE GOVERNANCE MEASURES

IVERIC bio, Inc. (f/k/a Ophthotech Corporation) ("Ophthotech" or the "Company") shall fully and faithfully adopt and implement all measures set forth in Section I below (the "Measures") not later than sixty (60) days following final settlement approval; provided, however, that a majority of the independent members of the Board may, subject to the requirements outlined below, amend or eliminate any one or more of these Measures if the independent members of the Board determine in a good faith exercise of their business judgment that the implementation or maintenance of the Measure(s) would be contrary to any applicable laws or regulations, including the Board's fiduciary duties. In such event, the independent directors, to the extent their fiduciary obligations allow based upon their good faith exercise of business judgment, shall adopt an amended or substitute measure that addresses the same goals, purposes and/or functions of the original Measure(s) as soon as practicable. Any changes made pursuant to the foregoing two sentences shall be published in the Company's next regular quarterly filing with the Securities and Exchange Commission. For the sake of clarity, nothing herein precludes the Board in its good faith exercise of business judgment from implementing amendments or modifications to provisions of the policies and procedures addressed by the Measures to the extent such amendments or modifications do not conflict with changes to such policies and procedures specifically implemented by the Measures.

Unless otherwise indicated, and subject to Paragraph 2.2 and 2.3 of the Stipulation of Settlement dated January 27, 2022 (the "Stipulation"), the Measures are for a period of four (4) years (the "Compliance Term").[1]

I. CORPORATE GOVERNANCE MEASURES TO BE IMPLEMENTED AND MAINTAINED BY IVERIC BIO, INC. (f/k/a/ OPHTHOTECH CORPORATION) AS A RESULT OF THE SETTLEMENT

- In addition to the prior Board changes implemented prior to September 3, 2021 in the context of the Derivative Actions (as referenced in Section II), the Board shall appoint another new independent board member. The Board shall retain a third-party search firm to identify a pool of candidates to fill the new board position.[2]

---

[1] Terms not defined herein shall have the definitions ascribed to them in the Stipulation.

[2] On January 5, 2022, the Board of Directors of the Company elected Christine Ann Miller as a Director of the Company. The election of Ms. Miller was intended to satisfy this Measure, and the Settling Parties agree the timing of the appointment (prior to final approval of the Settlement Agreement) shall not be used as a basis for any party to assert that the appointment of Ms. Miller does not satisfy this Measure.

- The Board shall ensure that at all times at least fifty-five percent (55%) of its members satisfy the requirements of Nasdaq Rule 5605(a)(2) for determining the "independence" of independent directors.

- The Board shall identify and designate a lead independent director in the event that the positions of CEO and Chairman are in the future held by the same individual. The responsibilities of the lead independent director, if one is designated, shall include (among other things): (i) working directly with management and the Board to ensure the preparation of meeting agendas, materials and schedules; (ii) assessing and advising the Board as to the quality, quantity, and timeliness of the information provided to the Board by management to assist the Board in performing its oversight duties; (iii) approving the agenda for, and moderating executive sessions of, the Board, and acting as principal liaison between the Board and management on sensitive issues; (iv) acting as liaison between the independent directors and the Chairman of the Board and management (however, each director is free to communicate directly with the Chairman of the Board and management); and (v) leading the Board's and the Compensation Committee's evaluation of the performance of the Company's CEO.

- In conducting a formal broad search for board of director candidates, the Board shall instruct any search firm engaged for such purpose that the initial pool of candidates shall be comprised of at least 50% of women and racially or ethnically diverse candidates, with at least 25% of those candidates being racially or ethnically diverse.

- The Board shall limit directors from serving as board members at "direct competitors" of the Company at any time.

    - "Direct competitors" shall be defined as "any company that engages in the research, development or commercialization of pharmaceutical or diagnostic products to treat (i) each of Stargardt disease, Best disease, leber congenital amaurosis (subtype 10), Usher syndrome type 2A-related inherited retinal diseases and rhodopsin-mediated autosomal dominant retinitis pigmentosa via any mechanism of action, (ii) ocular diseases whose primary mechanism of action is directed at the C5 molecule and/or its receptor or (iii) GA or AMD whose primary mechanism of action is directed at the HtrA1 enzyme."

- Absent extenuating circumstances, directors shall be required to attend either in person or virtually the annual shareholder meeting.

- The Company shall adopt a formal Charter for the management-level Disclosure Committee, which is attached hereto as Exhibit 1, reflecting the duties and responsibilities of the Disclosure Committee. The Charter shall provide, among other duties and responsibilities of the Disclosure Committee, that the Disclosure Committee is responsible for:

- Reviewing in advance the Company's quarterly earnings press releases and related materials (such as earnings conference call scripts) with respect to the adequacy and accuracy of the disclosures included therein;

- Reviewing transcripts of analyst conference calls and other investor presentations with respect to the accuracy of any disclosures made, advising the Audit Committee of any corrections that the Disclosure Committee determines need to be made, and oversight with respect to the drafting of any required corrective disclosures;

- Preparing and submitting to the Board a written report whenever any new material disclosure risks are identified concerning developments in the Company's clinical trials and drug approval efforts;

- Providing a written report to the Audit Committee, at least quarterly, regarding potential or actual material disclosure issues identified; and

- Providing a report to the Board, at least annually, summarizing its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Research and Development Committee (which was created in the context of the Derivative Actions) shall be amended to provide (among other things) that the Research and Development Committee will be responsible for: (i) reviewing and evaluating the design of the Company's clinical trials; (ii) tracking and evaluating the progress of all ongoing clinical trials; (iii) tracking the Company's ongoing relationships with any regulatory agency governing the clinical trials, including without limitation, the FDA; and (iv) working in conjunction with the Company's management-level Disclosure Committee and the Audit Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the status of any clinical trials undertaken by the Company, as well as communications with any regulatory agency governing the clinical trials, including without limitation, the FDA. The Research and Development Committee shall ensure that the Audit Committee and the Board are promptly made aware when any issues arising out of a clinical trial are considered material by the Research and Development Committee. The Research and Development Committee shall report at least annually to the Board with respect to its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Audit Committee shall be amended to include the following additional responsibilities:

  - The Audit Committee shall receive quarterly (and more often as warranted) updates from the Chief Financial Officer and/or the Company's management-level Disclosure Committee regarding the efforts of the Disclosure Committee. The Audit Committee shall work in conjunction with the Disclosure Committee and the Research and Development Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the

status of any clinical trials undertaken by the Company, as well as interactions with the FDA.

- The Audit Committee shall receive quarterly (and more often as necessary) updates from the Company's management on its risk management process. The Audit Committee shall report to the Board whenever any material risks relating to the Company's legal and/or regulatory compliance are identified, including with respect to recommendations regarding proposals for mitigating these risks, as well as relevant considerations relating to the Company's public disclosures of these risks.

- The Audit Committee shall receive reports from and coordinate with the Research and Development Committee regarding the integrity and accuracy of the Company's press releases and regulatory filings with respect to its clinical trials and studies. In the event the Research and Development Committee presents the Audit Committee with information concerning any developments related to a clinical trial that are sufficiently material to trigger a disclosure obligation, the Audit Committee shall assess whether any corrective or other disclosures are required.

- The Audit Committee shall receive annually a report listing all trades in the Company's securities engaged in by Section 16 officers of the Company.

- The Charter of the Nominating and Corporate Governance Committee shall be amended to provide that the Committee shall meet either in-person or virtually with each prospective new Board member prior to his or her nomination to the Board.

- The Charter of the Compensation and Talent Strategy Committee shall be amended to provide that: (i) in its consideration of compensation recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; (ii) in its consideration of severance arrangements recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; and (iii) the Committee shall consist of at least three (3) members.

- As an initial action item following the Company's commercialization of one or more of its therapeutic product candidates ("commercialization"), in the event the Company does not yet have a Chief Compliance Officer, the Company will appoint a Chief Compliance Officer as soon as is practicable, unless the Audit Committee, in conjunction with input from an outside independent consultant, determines in good faith that it is not in the Company's best interests, taking into account, among other considerations, the regulatory compliance obligations and financial resources of the Company. In the event the Company has not appointed a Chief Compliance Officer within six (6) months of commercialization, the Audit Committee shall provide a report regarding its determinations, the reasons for

not appointing a Chief Compliance Officer, and how the duties of a Chief Compliance Officer otherwise will be fulfilled by other existing positions to the Board.

- The Insider Trading Policy shall be amended to incorporate the following revisions, which are reflected in the amended Insider Trading Policy attached hereto as Exhibit 2:

    - The Company shall undertake an annual review reasonably intended to ensure that the Insider Trading Policy remains up-to-date with respect to insider trading laws and regulations.

    - The Company shall obtain annual written certifications from directors and executive officers indicating that those individuals have read and understood the terms of the Insider Trading Policy.

    - In the next quarterly filing following the approval of a new or amended Rule 10b5-1 plan for any director or executive officer, the Company shall disclose: (1) the name of the plan enrollee; (2) the date the plan was entered into; and (3) the date the plan expires, if applicable.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, during the pendency of any Company-funded open market stock buy-back program, no director or officer subject to reporting obligations under Section 16 of the Exchange Act shall be permitted to sell stock of the Company.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, officers subject to reporting obligations under Section 16 of the Exchange Act shall be prohibited from trading securities of the Company for the period of time beginning no later than the fifteenth (15th) day of the last month of each quarter and ending upon the completion of the second full trading day after the public announcement of earnings each quarter.

    - Any failure to comply with the Insider Trading Policy by any employee of the Company will result in an assessment by the Company concerning appropriate disciplinary action, which may include reimbursement for any fines, fees, or expenses incurred by the Company as a result of any noncompliance with the Insider Trading Policy, cancellation of outstanding stock options, disqualification from performance-based compensation, and employee discipline up to and including termination.

- The Clawback Policy shall be amended to provide the following, which is reflected in the amended Clawback Policy attached hereto as Exhibit 3:

    - Upon any restatement of the Company's financial results, the Board shall oversee an investigation reasonably intended to assess (1) whether any compensation, including in particular any incentive-based compensation (including stock options awarded as compensation), was paid to the Company's CEO, CFO, or any other executive officer on the basis of any misstated financial results; and (2) whether the

restatement was caused by fraud or intentional misconduct (as defined below in Exhibit 3) of the CEO, CFO, or any other executive officer.

- The Company shall disclose in its Compensation Discussion and Analysis a summary of the Board's investigation.

- The Board shall maintain and publish on the Company's website the following policies (as revised, where appropriate) for the entirety of the Compliance Term:
  - Insider Trading Policy
  - Related Person Transactions Policy
  - Clawback Policy

- The Code of Business Conduct and Ethics shall be amended to require that the Company institute mandatory annual employee training concerning applicable policies and codes of conduct, as appropriate given the employee's role within the Company.

- The Board shall maintain the provision in the Corporate Governance Guidelines that requires new directors to participate in the Company's orientation program for new directors.

- The Board shall amend the Corporate Governance Guidelines to require director participation in continuing education for directors, as the Board determines appropriate.

- The Board shall publish the revised Corporate Governance Guidelines and Code of Business Conduct and Ethics on the Company's website and include a link to those documents in the Company's proxy statements.

- The Board shall publish all Board committee charters, as revised, on the Company's website for the at least the duration of the Compliance Term.

- In the event that a final non-appealable judgment is entered against defendant Guyer and/or defendant Patel following summary adjudication or trial, including the conclusion of any and all appeals, in *Micholle v. Ophthotech Corporation, et al.*, Case No. 1:17-cv-00210-VSB-GWG (S.D.N.Y.) (the "Securities Class Action") for violation(s) of federal securities laws in which defendant Guyer and/or defendant Patel is found to have acted willfully in bad faith, Ophthotech shall, to the extent not inconsistent with applicable legal obligations, including but not limited to the Company's legal obligations to defendants Guyer and Patel contained in the Company's Fourth Amended and Restated Certificate of Incorporation, Paragraph TENTH, pursue sums previously paid pursuant to the Company's advancement and/or indemnification obligations to or for the benefit of the defendant(s) against whom such a final non-appealable judgment is entered.

II. CORPORATE GOVERNANCE ENHANCEMENTS AND OTHER CHANGES ALREADY IMPLEMENTED

- The Derivative Actions were a factor considered by the Company and its Board in connection with modifications it made to its board composition and structure in the period between (1) the filing of such litigation and the transmittal of litigation demands and (2) the parties' agreement in principle in connection with mediation to settle these Derivative Actions. Such modifications include the appointment of new, non-defendant directors to fill vacancies created by director departures.

- Concerns, including as expressed by the derivative plaintiffs in litigation and the demanding shareholders in correspondence and demands, were substantial contributing factors to the following corporate governance measures and enhancements:

    - Adoption of the Clawback Policy

    - Adoption of the Stock Retention and Ownership Guidelines

    - Amendments to the Code of Business Conduct and Ethics

EXHIBIT A-1

CONFIDENTIAL - SUBMITTED FOR SETTLEMENT DISCUSSION PURPOSES ONLY SUBJECT TO RULE 408 OF THE FEDERAL RULES OF EVIDENCE

IVERIC BIO, INC.

DISCLOSURE COMMITTEE CHARTER

I. POLICY REGARDING PUBLIC DISCLOSURES

The Company's policy is to comply fully and timely with all of its disclosure obligations under applicable securities laws and stock exchange requirements. To that end, the Company maintains "disclosure controls and procedures" (as defined in Section III below) that are designed to ensure that all information that may be required to be disclosed is:

- reported to the persons within the Company who are responsible for the preparation of the Company's SEC reports and other public communications;
- analyzed to determine whether disclosure is appropriate; and
- if appropriate, disclosed in a timely and accurate manner and in compliance with the SEC's reporting requirements and Regulation FD.

This document summarizes the principal disclosure controls and procedures that the Company has established and maintains.

II. DISCLOSURE COMMITTEE

A. Purpose

The Company has a Disclosure Committee, the purpose of which is to (1) consider the materiality of information and assist in the timely determination of the Company's disclosure obligations, (2) assist the Company in fulfilling its obligation to maintain disclosure controls and procedures and (3) assist the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") in fulfilling their obligations to design, establish, maintain and evaluate the effectiveness of the Company's disclosure controls and procedures.

B. Membership

The Disclosure Committee consists of employees of the Company selected from time to time by the Company's CEO and CFO. Except as otherwise determined by the CEO and CFO, the Disclosure Committee includes employees fulfilling the following functional areas:

- the Company's president;
- if other than the CFO, the Company's principal accounting officer or controller;

- once hired, the head of the Company's risk management and/or internal audit functions;
- the Company's senior research and development officer(s);
- the Company's chief operating officer;
- the Company's senior vice president, regulatory affairs and pharmacovigilance;
- once hired, the Company's senior commercial operations officer;
- the Company's senior business development officer;
- the Company's senior investor relations officer;
- the Company's senior human relations officer;
- the Company's vice president, project management;
- the Company's senior vice president, manufacturing; and
- such other employees as the CEO or CFO may designate from time to time.

In addition, the Company's General Counsel participates in Disclosure Committee meetings, receives copies of drafts and other materials distributed to the Disclosure Committee and provides legal counsel to the Disclosure Committee.

In selecting members of the Disclosure Committee, the CEO and CFO take into account an individual's access to, and knowledge of, information that may require public disclosure. The CEO and CFO periodically report to the Company's Board of Directors (or to a committee thereof designated by the Board of Directors) as to the identity of the members of the Disclosure Committee and the Disclosure Committee's responsibilities.

C. Responsibilities

The responsibilities of the Disclosure Committee include the following:

- Review in advance the Company's quarterly earnings press release and related materials (such as analyst conference call scripts) with respect to the adequacy and accuracy of the disclosures included therein.
- Review transcripts of analyst conference calls and other investor presentations with respect to the accuracy of any disclosures made,

advising the Audit Committee of any corrections that the Disclosure Committee determines need to be made, and oversight with respect to the drafting of any required corrective disclosures.

- Prepare and submit to the Board of Directors a written report whenever any new material disclosure risks are identified concerning developments in the Company's clinical trials and drug approval efforts.

- Provide a written report to the Audit Committee, at least quarterly, regarding potential or actual material disclosure issues identified.

- Provide a report to the Board of Directors, at least annually, summarizing its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- Coordinate and oversee the formulation and documentation of the Company's disclosure controls and procedures (including the Company's internal control over financial reporting to the extent they relate to information required to be publicly disclosed by the Company).

- Participate, together with the CEO and CFO, in an evaluation of the effectiveness of the Company's disclosure controls and procedures as of the end of each period to which an annual report on Form 10-K or quarterly report on Form 10-Q relates, as contemplated by Rules 13a-14 and 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act").

- Periodically review and assess the adequacy of the Company's disclosure policy and guidelines, including, without limitation, the Company's policies regarding public disclosure of material nonpublic information.

- Coordinate and oversee the process of preparing the Company's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and annual reports to stockholders (each, an "SEC Document").

- Review drafts of the SEC Documents and of such other disclosure documents (whether in the form of SEC filings, press releases, corporate website postings or other public communications) as the CEO or CFO may from time to time request.

The CEO and CFO may assign additional responsibilities to the Disclosure Committee as the CEO and CFO deem appropriate.

D. Procedures and Operation

The Disclosure Committee operates under the supervision of the CEO and CFO.

The members of the Disclosure Committee carry out their responsibilities on a continuous basis using such procedures as they deem appropriate, including, without limitation, holding formal or informal meetings, conducting telephone conferences or using other methods of communications.

At least once prior to the filing date of an SEC report requiring certification under Rule 13a-14 under the Exchange Act, the Disclosure Committee formally meets with the CEO and CFO to (1) report on the Disclosure Committee's activities since the last formal meeting with the CEO and CFO, (2) review the results of the evaluation of the Company's disclosure controls and procedures as of the last day of the period to which the SEC report relates, and (3) discuss the adequacy and effectiveness of the Company's disclosure controls and procedures.

The Disclosure Committee may designate one of its members as the primary coordinator of the Disclosure Committee's activities, including scheduling meetings, establishing meeting agendas and maintaining a record of the Disclosure Committee's activities.

The Disclosure Committee is afforded full access to all of the Company's books, records, facilities and personnel. In addition, the members of the Disclosure Committee are authorized to consult directly with the Company's outside securities counsel to the extent they deem appropriate. In light of the nature and objectives of the Disclosure Committee, the Disclosure Committee does not vote on the matters it addresses and has no quorum requirements.

III. DISCLOSURE CONTROLS AND PROCEDURES

A. Definition

The term "*disclosure controls and procedures*" is defined by Rule 13a-15 under the Exchange Act and means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the 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 SEC'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 CEO and CFO, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

B. Preparation of SEC Periodic Reports on Forms 10-K and 10-Q

The key elements of the Company's disclosure controls and procedures relating to SEC periodic reports on Forms 10-K and 10-Q are as follows:

- Distribution of a timetable for the preparation of each periodic report and related earnings release, including identification of responsible parties, dates for distribution of drafts and submission of comments, meetings of the Disclosure Committee and Audit Committee and other significant aspects of the preparation process.

- Meetings with and/or collection of financial and other material information from business unit heads in order to prepare the periodic report.

- Meetings between representatives of the finance department and independent auditors to discuss material accounting issues affecting the financial statements and periodic report, including accounting policies, judgments and estimates and any changes to accounting standards.

- Distribution of draft earnings release for review and comment to the Disclosure Committee, all relevant internal department managers, the independent auditors, outside securities counsel and the Audit Committee.

- An Audit Committee meeting, where: (1) management presents results of operations and financial position for the period; (2) the independent auditors report on the AU 722 review or year-end audit; (3) participants discuss accounting policies, judgments and estimates; (4) the Audit Committee meets directly with auditors without management present; and (5) the Audit Committee discusses the draft earnings release.

- Performance of technical compliance check of the draft periodic report and preparation of responses to any previously received SEC comments.

- Review by the Disclosure Committee of all categories of Form 8-K reportable events in order to identify whether the Company properly identified all Form 8-K reportable events that occurred during the past quarter.

- With respect to annual reports on Form 10-K, the holding of at least one "drafting session" to review and discuss the draft annual report.

- Distribution of the draft periodic report for review and comment to:

  - relevant business unit and functional heads (identifying, where appropriate, particularly relevant sections for review, and obtaining from each reviewing person confirmation that the portions of the report relevant to such person's areas of responsibility are fairly and accurately presented, and do not omit any material information required to be disclosed);

  - the Disclosure Committee, CEO and CFO;

  - the independent auditors and outside securities counsel; and

  - the Audit Committee and, with respect to Forms 10-K, the full Board of Directors.

- Report of the CEO and CFO to the Audit Committee and independent auditors regarding the evaluation of internal control over financial reporting and disclosure controls and procedures conducted by or with the participation of the CEO and CFO.

- Final review of periodic report by CEO and CFO, followed by execution and certification thereof.

C. <u>Preparation of Current Reports on Form 8-K</u>

The key elements of the Company's disclosure controls and procedures relating to current reports on Form 8-K are as follows:

- Identification of multiple persons within the Company who are most likely to first become aware of each type of Form 8-K reportable event and the designation of such persons as the "Disclosure Coordinators" with respect to such reportable events.

- Training of all Disclosure Coordinators regarding (1) Form 8-K requirements (including the making of materiality assessments), (2) the process for internally communicating information about events that might trigger a Form 8-K reporting requirement, and (3) the specific reportable events for which such person has been identified as a Disclosure Coordinator.

- Review by the Disclosure Committee of all reports from the Disclosure Coordinators of events that might trigger a Form 8-K requirement so that a timely decision may be made regarding whether a Form 8-K should be filed.

- To the extent practicable in light of the filing deadline, distribution of the draft Form 8-K for review and comment to:
  - relevant business unit and functional heads, if any (including obtaining from each reviewing person confirmation that the portions of the report relevant to such person's areas of responsibility are fairly and accurately presented, and do not omit any material information required to be disclosed);
  - the Disclosure Committee, CEO and CFO;
  - the independent auditors and the Audit Committee (to the extent the Form 8-K relates to financial matters);
  - outside securities counsel; and
  - any other relevant parties, as determined by the Disclosure Committee, the CEO or the CFO.
- Performance of technical compliance check of the draft Form 8-K.
- Final review of each Form 8-K by the CEO, CFO or another executive officer of the Company, followed by execution thereof by a duly authorized officer.

D. <u>Preparation of Proxy Statements and Annual Report to Stockholders</u>

The key elements of the Company's disclosure controls and procedures relating to proxy statements and those portions of the annual report to stockholders that are not a part of the annual report on Form 10-K (the "Proxy Documents") are as follows:

- Distribution of a timetable for the preparation of the Proxy Documents, including identification of responsible parties, dates for distribution of drafts and submission of comments, meetings of the Disclosure Committee and other significant aspects of the preparation process.
- Distribution and collection of Directors', Officers' and 5% Stockholders' Questionnaires ("D&O Questionnaires").
- Collection of information from Board of Director minutes, Compensation Committee and Audit Committee minutes, corporate compensation and equity incentive records, D&O Questionnaires, Schedules 13D and 13G, department managers and other resources, as necessary.

- Communication with members of Compensation Committee and Audit Committee to discuss information to be included in their respective committee reports. Distribution of draft Compensation Committee Report to Compensation Committee members and distribution of draft Audit Committee Report to Audit Committee members, for review, comment and approval.

- Communication with members of Compensation Committee and management to discuss information to be included in Compensation Discussion and Analysis (the "CD&A"). Distribution of draft CD&A to Compensation Committee members for review and comment.

- Performance of technical compliance check of draft Proxy Documents and preparation of responses to any previously received SEC comments.

- Distribution of draft Proxy Documents for review and comment to:

  - relevant business unit and functional heads (identifying, where appropriate, particularly relevant sections for review, and obtaining from each reviewing person confirmation that the portions of the Proxy Documents relevant to such person's areas of responsibility are fairly and accurately presented, and do not omit any material information required to be disclosed);

  - the Disclosure Committee, CEO and CFO;

  - the independent auditors and outside securities counsel; and

  - the full Board of Directors.

- Final review of Proxy Documents by CEO and CFO.

IV. INTERNAL CONTROLS

A. Definition

The term *"internal control over financial reporting"* is defined by Rule 13a-15 under the Exchange Act and means a process designed by, or under the supervision of, the Company's CEO and CFO and effected by the Company's Board of Directors, management or other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

B. Description of the Company's Internal Control over Financial Reporting

The key elements of the Company's internal control over financial reporting that relate to the Company's disclosure controls and procedures include the following:

- the capture of financial information in a Company-wide reporting system that generates financial reports that are regularly reviewed by various members of management;

- corporate policies limiting signing authority for significant transactions and contracts to a selected group of Company employees and requiring legal review of significant contracts prior to their execution;

- the periodic review and comparison of actual results to internal budgets and plans; and

- the various activities conducted by the Company's internal auditors.

EXHIBIT A-2

CONFIDENTIAL - SUBMITTED FOR SETTLEMENT DISCUSSION PURPOSES ONLY SUBJECT TO RULE 408 OF THE FEDERAL RULES OF EVIDENCE

IVERIC BIO, INC.

Insider Trading Policy

1. BACKGROUND AND PURPOSE

The federal securities laws prohibit any member of the Board of Directors (a "Director"), officer (as defined in Rule 16(a)-1(f) under the Securities Exchange Act of 1934 (the "Exchange Act"), an "executive officer"), or employee of IVERIC bio, Inc. (together with its subsidiaries, the "Company") from purchasing or selling Company securities on the basis of material nonpublic information concerning the Company, or from tipping material nonpublic information to others. These laws impose severe sanctions on individuals who violate them. In addition, the Securities and Exchange Commission has the authority to impose large fines on the Company and on the Company's Directors, executive officers and controlling stockholders if the Company's employees engage in insider trading and the Company has failed to take appropriate steps to prevent it (so-called "controlling person" liability).

This insider trading policy is being adopted in light of these legal requirements, and with the goal of helping:

- prevent inadvertent violations of the insider trading laws;
- avoid embarrassing proxy disclosure of reporting violations by persons subject to Section 16 of the Exchange Act;
- avoid even the appearance of impropriety on the part of those employed by, or associated with, the Company;
- protect the Company from controlling person liability; and
- protect the reputation of the Company, its Directors and its employees.

As detailed below, this policy applies to family members and certain other persons and entities with whom Directors and employees have relationships. However, nothing in this policy is applicable to transactions by the Company itself.

1.1 What Type of Information is "Material"?

Information concerning the Company is considered "material" if there is a substantial likelihood that a reasonable shareholder would consider the information important in making a decision to buy or sell the Company's securities. Stated another way, there must be a substantial likelihood that a reasonable shareholder would view the information as having significantly altered the "total mix" of information available about the Company. Material information can include positive or negative information about the Company. Information concerning any of the following subjects, or the Company's plans with respect to any of these subjects, would often be considered material:

- the Company's revenues or earnings;
- a merger or acquisition or licensing transaction involving the Company;
- a change in management or the Board of Directors of the Company;
- the Company's decision to commence or terminate the payment of cash dividends;
- the public or private sale of a significant amount of securities of the Company;
- the establishment of a program to repurchase securities of the Company;
- a stock split;
- a default on outstanding debt of the Company or a bankruptcy filing;
- a new product release or a significant development, invention or discovery;
- information concerning upcoming FDA actions or other significant regulatory developments, including significant new clinical trial results or a significant product recall;
- a significant licensing or collaboration agreement, or serious discussions regarding such an agreement;
- the loss, delay or gain of a significant contract, sale or order or other important development regarding customers or suppliers;
- a cybersecurity incident or breach resulting in unauthorized access, loss, damage or compromise of Company data, information or network systems;
- any litigation or dispute to which the Company may be a party;
- a conclusion by the Company or a notification from its independent auditor that any of the Company's previously issued financial statements should no longer be relied upon; or
- a change in or dispute with the Company's independent auditor.

This list is illustrative only and is not intended to provide a comprehensive list of circumstances that could give rise to material information.

1.2 When is Information "Nonpublic"?

Information concerning the Company is considered nonpublic if it has not been disseminated in a manner making it available to investors generally.

Information will generally be considered nonpublic unless (1) the information has been disclosed in a press release, in a public filing made with the Securities and Exchange Commission (such as a Report on Form 10-K, Form 10-Q or Form 8-K), or through a news wire service or daily newspaper of wide circulation, and (2) a sufficient amount of time has passed so that the information has had an opportunity to be digested by the marketplace.

1.3 Annual Review and Certifications

The Company shall undertake an annual review reasonably intended to ensure that the Insider Trading Policy remains up-to-date with respect to insider trading laws and regulations.

The Company shall obtain annual written certifications from directors and executive officers indicating that those individuals have read and understood the terms of the Insider Trading Policy.

2. PROHIBITIONS RELATING TO TRANSACTIONS IN THE COMPANY'S SECURITIES

2.1 Covered Persons. This Section 2 applies to:

- all Directors;
- all employees;
- all family members of Directors and employees who share the same address as, or are financially dependent on, the Director or employee and any other person who shares the same address as the Director or employee (other than (x) an employee or tenant of the Director or employee or (y) another unrelated person whom the General Counsel determines should not be covered by this policy); and
- all corporations, partnerships, trusts or other entities controlled by any of the above persons, unless the entity has implemented policies or procedures designed to ensure that such person cannot influence transactions involving Company securities by the entity.

2.2 Prohibition on Trading While Aware of Material Nonpublic Information.

(a) Prohibited Activities. Except as provided in Section 2.2(b), no person or entity covered by Section 2 may:

- purchase, sell or donate any securities of the Company while he or she is aware of any material nonpublic information concerning the Company or recommend to another person that they do so;
- disclose to any other person any material nonpublic information concerning the Company if it is reasonably foreseeable that such

person may misuse that information, such as by purchasing or selling Company securities or tipping that information to others;

- purchase, sell or donate any securities of another company while he or she is aware of any material nonpublic information concerning such other company which he or she learned in the course of his or her service as a Director or employee of the Company or recommend to another person that they do so; or

- disclose to any other person any material nonpublic information concerning another company which he or she learned in the course of his or her service as a Director or employee of the Company if it is reasonably foreseeable that such person may misuse that information, such as by purchasing or selling securities of such other company or tipping that information to others.

(b) Exceptions. The prohibitions in Sections 2.2(a) and 2.3 on purchases, sales and donations of Company securities do not apply to:

- exercises of stock options or other equity awards or the surrender of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligations, in each case in a manner permitted by the applicable equity award agreement; provided, however, that the securities so acquired may not be sold (either outright or in connection with a "cashless" exercise transaction through a broker) while the employee or Director is aware of material nonpublic information or during a blackout period (as defined in Section 2.3(b));

- acquisitions or dispositions of Company common stock under the Company's 401(k) or other individual account plan that are made pursuant to standing instructions not entered into or modified while the employee or Director is aware of material nonpublic information or during a blackout period;

- other purchases of securities from the Company (including purchases under any employee stock purchase plan of the Company) or sales of securities to the Company;

- bona fide gifts, unless the donor has reason to believe that the recipient intends to sell the securities while the donor is aware of material nonpublic information or during a blackout period; and

- purchases or sales made pursuant to a binding contract, written plan or specific instruction (a "trading plan") which is adopted and operated in compliance with Rule 10b5-1; provided such trading plan: (1) is in writing; (2) was submitted to the Chief Financial Officer and/or General Counsel for review by the Company prior

to its adoption; and (3) was not adopted while the employee or Director was aware of material nonpublic information or during a blackout period; and provided further that (i) if such trading plan is adopted within two weeks prior to the commencement of a regular blackout period (as defined in Section 2.3(a)), trades may not occur pursuant to such trading plan prior to the termination of such regular blackout period, (ii) any trade under such trading plan shall not occur until at least 30 days after the date of such trading plan, and (iii) if such trading plan is amended in any material respect or terminated, trades may not occur pursuant to such trading plan or a subsequent trading plan until at least 30 days after such amendment or termination.

(c) Disclosure of Rule 10b5-1 Plans. In the next quarterly filing following the approval of a new or amended Rule 10b5-1 plan for any director or executive officer, the Company shall disclose: (1) the name of the plan enrollee; (2) the date the plan was entered into; and (3) the date the plan expires, if applicable.

(d) Application of Policy After Cessation of Service. If a person ceases to be a Director or employee of the Company at a time when he or she is aware of material nonpublic information concerning the Company, the prohibition on purchases, sales or donations of Company securities in Section 2.2(a) shall continue to apply to such person until that information has become public or is no longer material.

2.3 Blackout Periods.

(a) Regular Blackout Periods. Except as provided in Section 2.2(b), no person or entity covered by this Section 2 may purchase, sell or donate any securities of the Company during the period beginning on the day immediately following the final day of each fiscal quarter and ending upon the completion of the second full trading day after the public announcement of earnings for such quarter (a "regular blackout period").

(b) Regular Blackout Periods for Section 16 Officers. Except as provided in Section 2.2(b), officers subject to reporting obligations under Section 16 of the Exchange Act shall be prohibited from trading securities of the Company for the period of time beginning no later than the fifteenth (15th) day of the last month of each quarter and ending upon the completion of the second full trading day after the public announcement of earnings each quarter.

(c) Corporate News Blackout Periods. The Company may from time to time notify Directors, executive officers and other specified employees that an additional blackout period (a "corporate news blackout period") is in effect in view of significant events or developments involving the Company. In such event, except as provided in Section 2.2(b), no such individual may purchase, sell or donate any securities of the Company during such corporate news blackout period or inform anyone else that a corporate news blackout period is in effect. (In this policy, regular blackout periods and corporate news blackout periods are each referred to as a "blackout period.")

(d) Company-funded Open Market Stock Buy-back Program. Except as provided in Section 2.2(b), during the pendency of any Company-funded open market stock buy-back program, no director or officer subject to reporting obligations under Section 16 of the Exchange Act shall be permitted to sell stock of the Company.

2.4 Prohibition on Pledges. No person or entity covered by this Section 2 may purchase Company securities on margin, borrow against Company securities held in a margin account, or pledge Company securities as collateral for a loan. However, an exception may be granted where a person wishes to pledge Company securities as collateral for a loan and clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities. Any person who wishes to pledge Company securities as collateral for a loan must submit a request for approval to the Chief Financial Officer or the General Counsel.

2.5 Prohibition on Short Sales and Derivative Transactions. No person or entity covered by this Section 2 may engage in any of the following types of transactions:

- short sales of Company securities, including short sales "against the box"
- purchases or sales of puts, calls or other derivative securities based on the Company's securities; or
- purchases of financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds) that are designed to hedge or offset and decrease the market value of the Company securities.

2.6 Partnership Distributions. Nothing in this policy is intended to limit the ability of a venture capital partnership or other similar entity with which a Director is affiliated to distribute Company securities to its partners, members or other similar persons. It is the responsibility of each affected Director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

2.7 Underwritten Public Offering. Nothing in this policy is intended to limit the ability of any person to sell Company securities as a selling stockholder in an underwritten public offering pursuant to an effective registration statement in accordance with applicable securities law.

3. ADDITIONAL PROHIBITIONS APPLICABLE TO DIRECTORS, EXECUTIVE OFFICERS AND DESIGNATED EMPLOYEES

3.1 Covered Persons. This Section 3 applies to:

- all Directors;
- all executive officers;
- such other employees as are designated from time to time by the Board of Directors, the Chief Executive Officer, the Chief Financial Officer or the

General Counsel as being subject to this Section 3 (the "Designated Employees");

- all family members of Directors, executive officers and Designated Employees who share the same address as, or are financially dependent on, the Director, executive officer or Designated Employee and any other person who shares the same address as the Director, executive officer or Designated Employee (other than (x) an employee or tenant of the Director, executive officer or Designated Employee or (y) another unrelated person whom the General Counsel determines should not be covered by this policy); and

- all corporations, partnerships, trusts or other entities controlled by any of the above persons, unless the entity has implemented policies or procedures designed to ensure that such person cannot influence transactions by the entity involving Company securities.

3.2 Notice and Pre-Clearance of Transactions.

(a) Pre-Transaction Clearance. No person or entity covered by this Section 3 (a "Pre-Clearance Person") may purchase or sell or otherwise acquire or dispose of securities of the Company, other than in a transaction permitted under Section 2.2(b), unless such person pre-clears the transaction with either the Chief Financial Officer or the General Counsel. A request for pre-clearance shall be made in accordance with the procedures established by the General Counsel. The Chief Financial Officer and the General Counsel shall have sole discretion to decide whether to clear any contemplated transaction. (The General Counsel shall have sole discretion to decide whether to clear transactions by the Chief Financial Officer or persons or entities subject to this policy as a result of their relationship with the Chief Financial Officer, and the Chief Financial Officer shall have sole discretion to decide whether to clear transactions by the General Counsel or persons or entities subject to this policy as a result of their relationship with the General Counsel.) All trades that are pre-cleared must be effected within five business days of receipt of the pre-clearance unless a specific exception has been granted by the General Counsel and/or the Chief Financial Officer. A pre-cleared trade (or any portion of a pre-cleared trade) that has not been effected during the five business day period must be pre-cleared again prior to execution. Notwithstanding receipt of pre-clearance, if the Pre-Clearance Person becomes aware of material non-public information or becomes subject to a blackout period before the transaction is effected, the transaction may not be completed.

(b) Post-Transaction Notice. Each person or entity covered by this Section 3 who is subject to reporting obligations under Section 16 of the Exchange Act shall also notify the Chief Financial Officer or the General Counsel (or his or her designee) of the occurrence of any purchase, sale or other acquisition or disposition of securities of the Company as soon as possible following the transaction, but in any event within one business day after the transaction. Such notification may be oral or in writing (including by e-mail) and should include the identity of the covered person, the type of transaction, the date of the transaction, the number of shares involved and the purchase or sale price.

(c) Deemed Time of a Transaction. For purposes of this Section 3.2, a purchase, sale or other acquisition or disposition shall be deemed to occur at the time the person becomes irrevocably committed to it (for example, in the case of an open market purchase or sale, this occurs when the trade is executed, not when it settles).

4. REGULATION BTR

If the Company is required to impose a "pension fund blackout period" under Regulation BTR, each Director and executive officer shall not, directly or indirectly sell, purchase or otherwise transfer during such blackout period any equity securities of the Company acquired in connection with his or her service as a director or officer of the Company, except as permitted by Regulation BTR.

5. PENALTIES FOR VIOLATION

Violation of any of the foregoing rules is grounds for disciplinary action by the Company, including termination of employment. In addition to any disciplinary actions the Company may take, insider trading can also result in administrative, civil or criminal proceedings which can result in significant fines and civil penalties, being barred from service as an officer or director of a public company, or being sent to jail.

Any failure to comply with the Insider Trading Policy by any employee of the Company will result in an assessment by the Company concerning appropriate disciplinary action, which may include reimbursement for any fines, fees, or expenses incurred by the Company as a result of any noncompliance with the Insider Trading Policy, cancellation of outstanding stock options, disqualification from performance-based compensation, and employee discipline up to and including termination.

6. COMPANY ASSISTANCE AND EDUCATION

6.1 Education. The Company shall take reasonable steps designed to ensure that all Directors and employees of the Company are educated about, and periodically reminded of, the federal securities law restrictions and Company policies regarding insider trading.

6.2 Assistance. The Company shall provide reasonable assistance to all Directors and executive officers, as requested by such Directors and executive officers, in connection with the filing of Forms 3, 4 and 5 under Section 16 of the Exchange Act. However, the ultimate responsibility, and liability, for timely filing remains with the Directors and executive officers.

6.3 Limitation on Liability. None of the Company, the Chief Financial Officer, the General Counsel or the Company's other employees will have any liability for any delay in reviewing, or refusal of, a trading plan submitted pursuant to Section 2.2(b), a request for pre-clearance submitted pursuant to Section 3.2(a) or a request to allow a pledge submitted pursuant to Section 2.4. Notwithstanding any review of a trading plan pursuant to Section 2.2(b) or pre-clearance of a transaction pursuant to Section 3.2(a), none of the Company, the Chief Financial Officer, the General Counsel or the Company's other employees assumes any liability for the legality or consequences of such trading plan or transaction to the person engaging in or adopting such trading plan or transaction.

EXHIBIT A-3

CONFIDENTIAL - SUBMITTED FOR SETTLEMENT DISCUSSION PURPOSES ONLY
SUBJECT TO RULE 408 OF THE FEDERAL RULES OF EVIDENCE

IVERIC BIO, INC.

Clawback Policy

In the event both:

(a) IVERIC bio, Inc. (the "Company") is required to prepare an accounting restatement for periods that end on or after the effective date of this policy due to material noncompliance of the Company with any financial reporting requirement under the U.S. federal securities laws; and

(b) the Board of Directors (or a duly established committee thereof), in its sole discretion, determines that an act or omission of a current or former executive officer of the Company contributed to the circumstances requiring the restatement and that such act or omission involved fraud or intentional misconduct (as defined below),

shall have occurred, then the Company will use reasonable efforts to recover from such person up to 100% (as determined by the Board or committee in its sole discretion as appropriate based on the conduct involved) of any incentive-based compensation (including stock options awarded as compensation) from the Company during the three-year period preceding the date on which the Company is required to prepare such accounting restatement.

Upon any restatement of the Company's financial results, the Board shall oversee an investigation reasonably intended to assess (1) whether any compensation, including in particular any incentive-based compensation (including stock options awarded as compensation), was paid to the Company's CEO, CFO, or any other executive officer on the basis of any misstated financial results; and (2) whether the restatement was caused by fraud or intentional misconduct (as defined below) of the CEO, CFO, or any other executive officer. The Company shall disclose in its Compensation Discussion and Analysis a summary of the Board's investigation.

The term "fraud or intentional misconduct" is intended to include reckless conduct (meaning any highly unreasonable act or omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and that is either known to the executive or is so obvious the executive must have been aware of it), but is not intended to include negligent conduct or grossly negligent conduct not meeting that definition. Further, the term "fraud or intentional misconduct" shall not include conduct in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the corporation (including an executive officer's good faith scientific or medical judgments).

This policy shall apply to incentive-based compensation that is granted after the adoption of this policy. This policy shall be interpreted in a manner that is consistent with any applicable rules or regulations adopted by the Securities and Exchange Commission or NASDAQ pursuant to Section 10D of the Securities Exchange Act of 1934 (the "Applicable Rules") and any other applicable law and shall otherwise be interpreted (including in the determination of amounts recoverable) in the business judgment of the Company's Board of Directors (or a duly established committee thereof). To the extent the Applicable Rules require recovery of incentive-

based compensation in additional circumstances besides those specified above, nothing in this policy shall be deemed to limit or restrict the right or obligation of the Company to recover incentive-based compensation to the fullest extent required by the Applicable Rules.

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB **[PROPOSED] ORDER PRELIMINARILY APPROVING DERIVATIVE SETTLEMENT AND PROVIDING FOR NOTICE**

WHEREAS, Plaintiff has moved, pursuant to Federal Rule of Civil Procedure 23.1, for an order: (i) preliminarily approving the settlement of the Derivative Actions, in accordance with a Stipulation of Settlement, dated January 27, 2022 (the "Stipulation" or "Settlement"), which, together with the Exhibits annexed thereto, sets forth the terms and conditions for a proposed Settlement and dismissal of the Derivative Actions with prejudice; and (ii) approving the dissemination of the Notice of Proposed Settlement and of Settlement Hearing and Summary Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions;

WHEREAS, all capitalized terms contained herein shall have the meanings as set forth in the Stipulation (in addition to those capitalized terms defined herein); and

WHEREAS, this Court, having considered the Stipulation and the Exhibits annexed thereto and having considered the arguments of the Settling Parties on the motion for preliminary approval of the Settlement;

NOW, THEREFORE, IT IS HEREBY ORDERED:

1. This Court does hereby preliminarily approve, subject to further consideration at the Settlement Hearing described below, the Stipulation and the Settlement set forth therein, including the terms and conditions for settlement and dismissal with prejudice of the Derivative Actions.

2. A hearing (the "Settlement Hearing") shall be held before this Court on _____, 2022, at __:___ __.m., at 40 Foley Square, New York, New York 10007, to determine whether the Settlement of the Derivative Actions on the terms and conditions provided for in the Stipulation is fair, reasonable, and adequate to IVERIC bio, Inc. f/k/a/ Ophthotech Corporation ("Ophthotech" or the "Company") and its stockholders and should be approved by the Court; whether the Order and Final Judgment as provided in paragraph 1.15 of the Stipulation should be entered herein; and whether the agreed amount of attorneys' fees and expenses to be paid by Defendants' insurers to Plaintiffs' Counsel should be approved.

3. The Court approves, as to form and content, the Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions annexed as Exhibit B-1 hereto (the "Long-Form Notice") and the Summary Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions annexed as Exhibit B-2 hereto (the "Summary Notice" and collectively with the Long-Form Notice, the "Notice"), and finds that the publication of the Long-Form Notice, Summary Notice, and Stipulation, substantially in the manner and form set forth in this Order, meets the requirements of Federal Rule of Civil Procedure 23.1 and due process, is the best notice practicable

under the circumstances, and shall constitute due and sufficient notice to all Persons entitled thereto.

4. Within ten (10) business days after the entry of this Order, Ophthotech shall cause the Stipulation of Settlement and a copy of the Long-Form Notice, substantially in the form annexed as Exhibit B-1 to the Stipulation, to be filed with the SEC along with an SEC Form 8-K or other appropriate filing, and shall publish the Summary Notice, substantially in the form annexed as Exhibit B-2 to the Stipulation, one time in the national edition of *Investors' Business Daily*. Ophthotech shall also publish the Stipulation of Settlement and Notice on an Internet page that Ophthotech shall create for this purpose, which shall be accessible via a link on the "Investor Relations" page of Ophthotech's website, the address of which shall be contained in the Long-Form Notice and Summary Notice.

5. All costs incurred in the filing, publishing, and posting of the Notice shall be paid by Ophthotech, and Ophthotech shall undertake all administrative responsibility for such filing, publication, and posting.

6. Not later than thirty-five (35) calendar days before the Settlement Hearing, Defendants' Counsel shall serve on Plaintiffs' Counsel and file with the Court proof, by affidavit or declaration, that it has complied with paragraph 4 above.

7. Ophthotech Stockholders shall be bound by all orders, determinations, and judgments of this Court concerning the Settlement, whether favorable or unfavorable to Ophthotech stockholders.

8. Pending final determination by the Court of whether the Settlement should be approved, this Court preliminarily bars and enjoins Plaintiffs and all other Ophthotech stockholders from commencing, instituting, filing, intervening in, participating in, receiving any

benefit from, or prosecuting any action, including without limitation any derivative action, asserting any of the Released Claims against any of the Released Persons. Except as otherwise provided for in the Stipulation, all proceedings and discovery in the Derivative Actions shall be stayed, and no party to the Derivative Actions or any Ophthotech stockholder shall file or prosecute any action or proceeding in any court or tribunal relating to the Settlement or asserting any of the Released Claims against the Released Persons.

9. All papers in support of the Settlement and the separately negotiated attorneys' fees and expenses shall be filed with the Court and served no later than twenty-eight (28) calendar days before the Settlement Hearing, and any reply briefs shall be filed with the Court seven (7) calendar days before the Settlement Hearing.

10. Any Current Company Stockholder may appear and show cause, if he, she, or it has any reason why the terms of the Settlement of the Derivative Actions, including the negotiated amount of attorneys' fees and expenses, should not be approved as fair, reasonable and adequate, or why the Order and Final Judgment should not be entered thereon; provided, however, that, unless otherwise ordered by the Court, no Person shall be heard or entitled to contest the approval of all or any of the terms and conditions of the Settlement, or, if approved, the Order and Final Judgment to be entered thereon approving the same, unless that Person has, at least twenty-one (21) calendar days before the Settlement Hearing, filed with the Clerk of the Court appropriate proof of Ophthotech stock ownership, along with written objections, including the basis therefore, and copies of any papers and brief in support thereof. All written objections and supporting papers must be submitted to the Court either by mailing them to:

Clerk of the Court
United States District Court
Southern District Of New York
40 Foley Square

New York, New York 10007

OR by filing them in person at any location of the United States District Court for the Southern District of New York.

All written objections must also be mailed to:

Plaintiffs' Counsel:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5040 Shoreham Place
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

Defendants' Counsel:

Michael G. Bongiorno
Jeremy T. Adler
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Counsel for Defendants and Nominal Defendant

Jordan D. Hershman
MORGAN, LEWIS & BOCKIUS LLP
One Federal Street
Boston, MA 02110

Counsel for Defendants David R. Guyer and Samir C. Patel

Any Person, including any Current Company Stockholder, who does not make an objection in the manner provided herein shall be deemed to have waived such objection and shall forever be foreclosed from making any objection to the fairness, reasonableness, or adequacy of the Settlement as incorporated in the Stipulation and to any attorneys' fees and expenses to be paid to

Plaintiffs' Counsel, unless otherwise ordered by the Court, but shall otherwise be bound by the Order and Final Judgment to be entered and the releases to be given.

11. Any attorney hired by a stockholder for the purpose of objecting to the Settlement must file a notice of appearance with the Clerk of the Court no later than twenty-one (21) calendar days before the Settlement Hearing.

12. Plaintiffs' Counsel and Defendants' Counsel are directed to promptly furnish each other with copies of any and all objections that are served upon them or otherwise come into their possession.

13. Neither the Stipulation nor the Settlement, including the Exhibits attached thereto, nor any act performed or document executed pursuant to or in furtherance of the Stipulation or the Settlement: (a) is or may be deemed to be or may be offered, attempted to be offered or used in any way as a concession, admission, or evidence of the validity of any Released Claims or any fault, wrongdoing, or liability of the Released Persons or Ophthotech; or (b) is or may be deemed to be or may be used as a presumption, admission, or evidence of any liability, fault or omission of any of the Released Persons or Ophthotech in any civil, criminal, administrative or other proceeding in any court, administrative agency, tribunal or other forum. Neither the Stipulation nor the Settlement, nor any act performed or document executed pursuant to or in furtherance of the Stipulation or the Settlement, shall be admissible in any proceeding for any purpose, except to enforce the terms of the Settlement, and except that the Released Persons may file or use the Stipulation, the Order and Final Judgment in any action that may be brought against them in order to support a defense or counterclaim based on principles of *res judicata*, collateral estoppel, full faith and credit, release, good faith settlement, standing, judgment bar or reduction, or any other theory of claim preclusion or issue preclusion or similar defense or counterclaim.

14. The Court reserves the right to adjourn the date of the Settlement Hearing or to hold the Settlement Hearing telephonically or via other remote method or to modify any other dates set forth herein without further notice to Ophthotech stockholders, and retains exclusive jurisdiction to consider all further applications arising out of or connected with the Settlement. The Court may approve the Settlement, with such modifications as may be agreed to by the Settling Parties, if appropriate, without further notice to Ophthotech stockholders.

IT IS SO ORDERED.

DATED: _____

_____
HONORABLE VERNON S. BRODERICK
UNITED STATES DISTRICT JUDGE

1551929

EXHIBIT B-1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB **NOTICE OF PENDENCY AND PROPOSED SETTLEMENT OF SHAREHOLDER DERIVATIVE ACTIONS**

TO: ALL RECORD HOLDERS AND BENEFICIAL OWNERS OF THE COMMON STOCK OF IVERIC BIO, INC. F/K/A/ OPHTHOTECH CORPORATION ("OPHTHOTECH" OR THE "COMPANY") AS OF JANUARY 27, 2022 (THE "RECORD DATE"), EXCLUDING DEFENDANTS AND ANY ENTITY IN WHICH THEY HAVE A CONTROLLING INTEREST AND OFFICERS AND DIRECTORS OF THE COMPANY AND THEIR LEGAL REPRESENTATIVES, HEIRS, SUCCESSORS, OR ASSIGNS.

PLEASE READ THIS NOTICE CAREFULLY AND IN ITS ENTIRETY. THIS NOTICE RELATES TO A PROPOSED SETTLEMENT AND DISMISSAL OF THE ABOVE-CAPTIONED DERIVATIVE ACTION AND OTHER SHAREHOLDER DERIVATIVE MATTERS AND CONTAINS IMPORTANT INFORMATION REGARDING YOUR RIGHTS. YOUR RIGHTS MAY BE AFFECTED BY THESE LEGAL PROCEEDINGS. IF THE COURT APPROVES THE SETTLEMENT, YOU WILL BE FOREVER BARRED FROM CONTESTING THE APPROVAL OF THE PROPOSED SETTLEMENT AND FROM PURSUING THE RELEASED CLAIMS.

IF YOU HOLD OPHTHOTECH COMMON STOCK FOR THE BENEFIT OF ANOTHER, PLEASE PROMPTLY TRANSMIT THIS DOCUMENT TO SUCH BENEFICIAL OWNER.

PLEASE NOTE THAT THERE IS NO CLAIMS PROCESS AND NO INDIVIDUAL STOCKHOLDER HAS THE RIGHT TO BE COMPENSATED AS A RESULT OF THE SETTLEMENT DESCRIBED BELOW.

A federal court authorized this Notice. This is not a solicitation from a lawyer.

I. WHY THE COMPANY HAS ISSUED THIS NOTICE

Notice is hereby provided to you of the proposed settlement (the "Settlement") of this stockholder derivative litigation and related matters. This Notice is provided by Order of the United States District Court for the Southern District of New York (the "Court"). It is not an expression of any opinion by the Court with respect to the truth of the allegations in the litigation or merits of the claims or defenses asserted by or against any party. It is solely to notify you of the terms of the proposed Settlement and your rights related thereto. The terms of the proposed Settlement are set forth in a written Stipulation of Settlement dated January 27, 2022 ("Stipulation").[1] A link to the Form 8-K filed with the SEC containing the text of the Stipulation may be found on Ophthotech's website at the Investor Relations page at _____.

Your rights may be affected by the settlement of the following matters, including without limitation all related stockholder demands: *Pacheco v. Guyer, et al.*, Case No. 1:18-cv-07999-VSB (S.D.N.Y.); *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup. Ct. N.Y. Cnty.); and the litigation demand made by shareholder Richard Waksman (together the "Derivative Actions"). Plaintiffs Luis Pacheco, Brian Ferber, Angel Ham and Richard Waksman ("Plaintiffs") (on behalf of themselves and derivatively on behalf of Ophthotech); individual defendants David R. Guyer, Glenn P. Sblendorio, David E. Redlick, Thomas Dyrberg, Axel Bolte, Michael J. Ross,

[1] Capitalized terms not otherwise defined shall have the same meanings as set forth in the Stipulation.

Samir C. Patel, Nicholas Galakatos; and nominal defendant Ophthotech (the "Defendants") (Plaintiffs and Defendants collectively, the "Settling Parties") have agreed upon terms to settle the above-referenced litigation and have signed the Stipulation setting forth those settlement terms.

On _____, 2022, at __:___ __.m., the Court will hold a hearing (the "Settlement Hearing") in the Federal Derivative Action. The purpose of the Settlement Hearing is to determine: (i) whether the Settlement is fair, reasonable, and adequate, including the separately negotiated amount of attorneys' fees and expenses for Plaintiffs' Counsel and the case contribution awards for the Plaintiffs, and should be finally approved; (ii) whether a final judgment should be entered and the Federal Derivative Action dismissed with prejudice pursuant to the Stipulation; and (iii) such other matters as may be necessary and proper under the circumstances.

II. OPHTHOTECH DERIVATIVE LITIGATION

A. The Federal Derivative Action

1. Federal Plaintiff Commences This Derivative Litigation

On August 31, 2018, Federal Plaintiff filed a Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment (the "Complaint") against individual defendants David R. Guyer, Glenn P. Sblendorio, David E. Redlick, Thomas Dyrberg, Axel Bolte, Michael J. Ross, Samir C. Patel, and Nicholas Galakatos (the "Individual Defendants"), on behalf of nominal defendant Ophthotech, captioned *Pacheco v. Guyer, et al*., C.A. No. 1:18-cv-07999-VSB (the "Federal Derivative Action").

Federal Plaintiff alleged that the Individual Defendants made and permitted the issuance of public statements that omitted material facts concerning: (i) the average lesion size and average visual acuity of patients in the control group for the Phase 2b trial for the Company's lead drug candidate, Fovista, which allegedly had the effect of overstating the drug's efficacy; and (ii)

changes made to the patient inclusion and exclusion criteria for the Fovista Phase 3 trials compared to the prior Phase 2b trial that allegedly adversely impacted the potential for replicating the positive results of the Phase 2b trial. Federal Plaintiff further alleged that the Individual Defendants' misstatements artificially inflated the Company's stock price, and that certain of the Individual Defendants sold their personally held shares of Ophthotech stock at those inflated prices.

Federal Plaintiff did not make a demand on Ophthotech's Board of Directors (the "Board") prior to filing suit and, instead, alleged that demand was excused as futile because there was reason to doubt (i) the disinterestedness of a majority of the Board members, based on the substantial threat of liability they faced; and (ii) the independence of a majority of the Board members, based on various business and financial entanglements.

B. The Court Denies the Defendants' Motion to Dismiss

On December 14, 2018, the Defendants filed a Motion to Dismiss the Verified Stockholder Derivative Complaint (the "Motion to Dismiss") pursuant to Federal Rule of Civil Procedure 23.1, arguing that Federal Plaintiff had failed to adequately allege that a pre-suit demand on the Board would have been futile. After the full briefing of the Motion to Dismiss, on September 19, 2019, the Court denied the Motion to Dismiss.

C. The Board Forms a Special Litigation Committee

In response to the denial of the Motion to Dismiss, on October 15, 2019, Ophthotech's Board established a Special Litigation Committee ("SLC"). Pursuant to a resolution of the Board, the SLC was "fully empowered to take and direct any and all actions on behalf of the Company with respect to [the Federal Derivative Action] and any stockholder derivative litigation [thereafter] filed that raises substantially similar allegations … or otherwise with respect to the allegations therein, including but not limited to investigating and making determinations

concerning or related to claims and allegations of [the Federal Derivative Action], determining whether the pursuit of the [Federal Derivative Action] is in the Company's best interests, causing the Company to pursue claims, causing the Company to seek the dismissal of claims, and seeking any form of relief or action by the Court with respect to the [Federal Derivative Action]."

D. The Parties Agree to Terms on Discovery and a Temporary Stay

Following extensive negotiations, the parties agreed on terms for (i) discovery; and (ii) a temporary stay in order to permit the SLC to conduct its investigation. Specifically, Defendants and the SLC, as appropriate and subject to the terms of the parties' stipulation, agreed to produce to Federal Plaintiff: (i) any final written SLC investigation report or presentation, if any, and any documents identified or referenced therein; (ii) in connection with such final report, if any, other SLC-related documents, including, *inter alia*, documents concerning the formation and independence of the SLC, minutes of relevant meetings of the Board and the SLC, and correspondence between SLC members and other members of the Board (hereinafter, the "SLC-related documents"); (iii) copies of all documents and written responses to discovery requests produced to the plaintiff in *Micholle v. Ophthotech Corporation, et al*., C.A. No. 1:17-cv-00210-VSB-GWG (the "Securities Action") in the form and manner in which such documents were produced to the Securities Action plaintiff; (iv) all written agreements regarding the scope of discovery to be produced by defendants in the Securities Action; and (v) all deposition transcripts generated in the Securities Action.

E. Discovery and Information-Gathering

Between June 2020 and April 2021, Ophthotech produced to Federal Plaintiff more than 100,000 documents constituting more than 4.2 million pages of material, which included transcripts of the depositions of percipient witnesses taken in the related Securities Class Action.

Federal Plaintiff's Counsel attest that they used search terms and custodial information to identify and compile, and then reviewed and evaluated, critical non-public documents and deposition testimony produced by Ophthotech concerning the allegations underlying this litigation.

On April 27, 2021, Federal Plaintiff's Counsel participated in a meeting with counsel for the SLC. Federal Plaintiff's Counsel made a presentation to SLC Counsel that addressed, among other things, (i) the factual allegations, the legal theories for recovery, and the damages alleged to have been suffered by the Company; (ii) corporate governance and other changes that had been made at the Company since the commencement of the Federal Derivative Action; and (iii) potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing. Federal Plaintiff's Counsel and SLC Counsel also discussed the status of the SLC's investigation and next steps, including the possibility of engaging in mediation to explore a potential resolution of the matter.

F. The Litigation Demands

1. The Waksman Demand

On June 22, 2018, Waksman made a demand for the inspection of documents of Ophthotech under 8 Del. C. §220 seeking documents concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "220 Demand"). In response to the 220 Demand, Ophthotech and counsel for Waksman negotiated and entered into a confidentiality agreement. In late October of 2018, Ophthotech provided approximately 2,200 pages of documents to Waksman and his counsel.

On January 23, 2019, subsequent to reviewing the documents, Waksman made a litigation demand on the Board, requesting that it take action to remedy breaches of fiduciary duties by the Individual Defendants in connection with alleged false and misleading statements concerning

Fovista and insider selling by defendants Patel, Guyer, Galakatos, and Sblendorio (the "Waksman Demand"). On March 7, 2019, counsel for Waksman was informed that the Board had formed a demand review committee (the "Demand Review Committee"). Subsequent to the making of the Waksman Demand, counsel for Waksman kept in regular contact with counsel for the Demand Review Committee and SLC concerning the Board's investigations and eventually settlement talks.

2. The Ferber/Ham Demand

On October 12, 2018, Ferber and Ham made a litigation demand upon the Board concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "Litigation Demand"). In response to the Litigation Demand, counsel for Ophthotech and counsel for Ferber and Ham exchanged correspondence. On November 30, 2018, counsel for the Company informed Ferber and Ham that the Board had formed the Demand Review Committee to examine the Litigation Demand. Later, that committee's membership was expanded to include Ophthotech director Adrienne Graves, and the SLC was appointed (as discussed above). Counsel for Ferber and Ham also requested that the Company obtain agreements tolling the statute of limitations from the individual defendants named in this Litigation Demand. The Company executed tolling agreements with the individuals. Thereafter, counsel for Ferber and Ham requested action by the SLC and a production of documents as to the investigation. Ferber and Ham subsequently filed an alleged demand-refused action in Supreme Court, New York County, captioned *Ferber, et al. v. Bolte, et al*., Index No. 154462/2021 on March 6, 2021 (the "State Derivative Action").

Thereafter, counsel for Ferber and Ham and counsel for the Defendants agreed to enter into a temporary stay of the State Derivative Action while the parties pursued global settlement talks. In addition, Ferber and Ham and counsel for the Defendants entered into a stipulation in

which the SLC agreed to produce to counsel for Ferber and Ham the SLC-related documents in accordance with the process provided for in connection with the Federal Derivative Action.

3. Settlement Efforts

On June 21, 2021, the Settling Parties and the SLC participated in an all-day mediation session with the Honorable Layn R. Phillips (Fmr.) and Niki Mendoza, nationally recognized mediators with extensive experience mediating complex stockholder disputes similar to the Derivative Actions, and both of Phillips ADR (the "Mediator"). The Settling Parties and the SLC made substantial progress at the mediation but were unable to resolve the Derivative Actions that day.

Over the course of the next month, the parties continued to engage in arm's-length negotiations regarding the terms of a potential settlement, including, in particular, corporate governance measures at Ophthotech that could form the basis for a settlement. These post-mediation negotiations were conducted via written and telephonic communications, with the continued oversight of the Mediator. The Settling Parties ultimately reached an agreement in principle on the material substantive terms of the Settlement, including the Corporate Governance Measures.

Thereafter, with the substantial involvement of the Mediator, the Settling Parties commenced negotiations regarding the attorneys' fees and expenses to be paid to Plaintiffs' Counsel. Despite their good faith efforts, the Settling Parties were unable to reach an agreement on an appropriate amount of attorneys' fees on their own. Accordingly, on September 1, 2021, the Mediator issued a mediator's recommendation for attorneys' fees and expenses in the amount of $2,450,000, to be paid to Plaintiffs' Counsel by the Individual Defendants' insurer(s) (the "Fee

and Expense Amount"). The Settling Parties agreed to the mediator's recommendation regarding the Fee and Expense Amount on September 3, 2021.

III. PLAINTIFFS' CLAIMS AND THE BENEFITS OF SETTLEMENT

Plaintiffs believe that the Derivative Actions have substantial merit, and Plaintiffs' entry into the Stipulation and Settlement is not intended to be and shall not be construed as an admission or concession concerning the relative strength or merit of the claims alleged in the Derivative Actions. However, Plaintiffs and Plaintiffs' Counsel recognize and acknowledge the significant risk, expense, and length of continued proceedings necessary to prosecute the Derivative Actions against the Individual Defendants through trial and possible appeals. Plaintiffs' Counsel also have taken into account the uncertain outcome and the risk of any litigation, especially in complex cases such as the Derivative Actions, as well as the difficulties and delays inherent in such litigation. Plaintiffs' Counsel are also mindful of the inherent problems of prevailing in the face of a potential motion to terminate by the SLC that was appointed by the Board here, the possible defenses to the claims brought in the Derivative Actions, and the difficulty of prevailing at trial in shareholder derivative litigation, generally.

Plaintiffs' Counsel have conducted extensive investigation and analysis, including, *inter alia*: (i) reviewing the voluminous non-public documents produced in the course of this litigation, including the discovery generated in the related Securities Action and produced to Federal Plaintiff; (ii) reviewing Ophthotech's press releases, public statements, U.S. Securities and Exchange Commission ("SEC") filings, and securities analysts' reports and advisories about the Company; (iii) reviewing related media reports about the Company; (iv) researching applicable law with respect to the claims alleged in the Derivative Actions and potential defenses thereto; (v) preparing and filing derivative complaints; (vi) preparing and sending inspection and litigation

demands; (vii) conducting damages analyses; (viii) evaluating the merits of, and the defendants' potential liability in connection with, the Securities Action; (ix) participating in a formal meeting and making a presentation to SLC Counsel regarding the factual allegations, the legal theories for recovery, the damages alleged to have been suffered by the Company, corporate governance and other changes that had been made at the Company, and potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing; (x) reviewing the Company's existing corporate governance policies and preparing comprehensive yet targeted settlement demands detailing proposed corporate governance measures to strengthen the Company's governance; (xi) participating in extensive settlement discussions, including an all-day mediation and continued follow-up communications with SLC Counsel and Defendants' Counsel and the Mediator; and (xii) negotiating the Stipulation and the exhibits hereto.

Based on Plaintiffs' Counsel's thorough review and analysis of the relevant facts, allegations, defenses, and controlling legal principles, Plaintiffs' Counsel believe that the Settlement set forth in the Stipulation is fair, reasonable, and adequate, and confers substantial benefits upon Ophthotech. Based upon Plaintiffs' Counsel's evaluation, Plaintiffs have determined that the Settlement is in the best interests of Ophthotech and have agreed to settle the Derivative Actions upon the terms and subject to the conditions set forth herein.

IV. DEFENDANTS' DENIALS OF WRONGDOING AND LIABILITY

Defendants have denied and continue to deny each and all of the claims and contentions alleged by Plaintiffs in the Derivative Actions, and the Individual Defendants have expressly denied and continue to deny all charges of wrongdoing or liability against them arising out of any of the conduct, statements, acts, or omissions alleged, or that could have been alleged, in the Derivative Actions. Defendants have also taken into account the uncertainty and risks inherent in

any litigation, especially in complex cases like the Derivative Actions. Defendants have, therefore, determined that it is in the best interests of Ophthotech for the Derivative Actions to be settled in the manner and upon the terms and conditions set forth in the Stipulation.

Neither the Stipulation, nor any of its terms or provisions, nor entry of the Judgment, nor any document or exhibit referenced by or attached to the Stipulation, nor any action taken to carry out the Stipulation, is, may be construed as, or may be used as evidence of the validity of any of the Released Claims or as an admission by or against the Individual Defendants of any fault, wrongdoing, or concession of liability whatsoever.

V. INDEPENDENT DIRECTOR APPROVAL

The members of the SLC, acting on behalf of the Company, have unanimously approved a resolution reflecting their determination, in an exercise of their business judgment, that: (a) Plaintiffs' litigation and settlement efforts in the Derivative Actions were a material and contributing factor in the Board's agreement to adopt, implement, and maintain the Corporate Governance Measures for the agreed term; (b) the Corporate Governance Measures reflected in **Exhibit A** to the Stipulation confer substantial benefits on the Company and its stockholders; and (c) the Settlement is fair, reasonable and in the best interests of the Company and its stockholders.

VI. TERMS OF THE PROPOSED DERIVATIVE SETTLEMENT

The principal terms, conditions, and other matters that are part of the Settlement, which is subject to approval by the Court, are summarized below. This summary should be read in conjunction with, and is qualified in its entirety by reference to, the text of the Stipulation and its accompanying Exhibits, which have been filed with the Court and are available at a link on Ophthotech's website at the Investor Relations page at _____.

In connection with the Settlement of the Derivative Actions, Ophthotech's Board shall adopt and maintain the corporate governance measures (the "Corporate Governance Measures") described below within sixty (60) days after the Court's final approval of the proposed Settlement. The Corporate Governance Measures shall remain in effect for a period of no less than four (4) years following final settlement approval, except for modifications required by applicable law, regulation, or fiduciary duty, or upon a Change in Control Event, in which case all duties and obligations to maintain the Corporate Governance Measures shall become subject to the good faith exercise of the succeeding board's or controlling group's or entity's business judgment. The Corporate Governance Measures may be amended or eliminated if a majority of the independent members of the Board determine in a good faith exercise of their business judgment that the implementation or maintenance of the Corporate Governance Measure(s) would be contrary to applicable laws or regulations, including the Board's fiduciary duties. In such event, the independent directors, to the extent their fiduciary obligations allow based upon their good faith exercise of business judgment, shall adopt an amended or substitute reform that addresses the same goals, purposes and/or functions of the original Corporate Governance Measure(s) as soon as practicable. Any changes made pursuant to this provision shall be published in the Company's next regular quarterly filing with the SEC.

CORPORATE GOVERNANCE MEASURES

1. **CORPORATE GOVERNANCE MEASURES TO BE IMPLEMENTED AND MAINTAINED BY IVERIC BIO, INC. (f/k/a/ OPHTHOTECH CORPORATION) AS A RESULT OF THE SETTLEMENT**

- In addition to the prior Board changes already implemented in the context of the Derivative Actions (as referenced in Section 2), the Board shall appoint another new independent

board member. The Board shall retain a third-party search firm to identify a pool of candidates to fill the new board position.[2]

- The Board shall ensure that at all times at least fifty-five percent (55%) of its members satisfy the requirements of Nasdaq Rule 5605(a)(2) for determining the "independence" of independent directors.

- The Board shall identify and designate a lead independent director in the event that the positions of CEO and Chairman are in the future held by the same individual. The responsibilities of the lead independent director, if one is designated, shall include (among other things): (i) working directly with management and the Board to ensure the preparation of meeting agendas, materials and schedules; (ii) assessing and advising the Board as to the quality, quantity, and timeliness of the information provided to the Board by management to assist the Board in performing its oversight duties; (iii) approving the agenda for, and moderating executive sessions of, the Board, and acting as principal liaison between the Board and management on sensitive issues; (iv) acting as liaison between the independent directors and the Chairman of the Board and management (however, each director is free to communicate directly with the Chairman of the Board and management); and (v) leading the Board's and the Compensation Committee's evaluation of the performance of the Company's CEO.

- In conducting a formal broad search for board of director candidates, the Board shall instruct any search firm engaged for such purpose that the initial pool of candidates shall be comprised of at least 50% of women and racially or ethnically diverse candidates, with at least 25% of those candidates being racially or ethnically diverse.

- The Board shall limit directors from serving as board members at "direct competitors" of the Company at any time.

    - "Direct competitors" shall be defined as "any company that engages in the research, development or commercialization of pharmaceutical or diagnostic products to treat (i) each of Stargardt disease, Best disease, leber congenital amaurosis (subtype 10), Usher syndrome type 2A-related inherited retinal diseases and rhodopsin-mediated autosomal dominant retinitis pigmentosa via any mechanism of action, (ii) ocular diseases whose primary mechanism of action is directed at the C5 molecule and/or its receptor or (iii) GA or AMD whose primary mechanism of action is directed at the HtrA1 enzyme."

[2] On January 5, 2022, the Board of Directors of the Company elected Christine Ann Miller as a Director of the Company. The election of Ms. Miller was intended to satisfy this Measure, and the Settling Parties agree the timing of the appointment (prior to final approval of the Settlement Agreement) shall not be used as a basis for any party to assert that the appointment of Ms. Miller does not satisfy this Measure.

- Absent extenuating circumstances, directors shall be required to attend either in person or virtually the annual shareholder meeting.

- The Company shall adopt a formal Charter for the management-level Disclosure Committee, which is attached hereto as Exhibit 1, reflecting the duties and responsibilities of the Disclosure Committee. The Charter shall provide, among other duties and responsibilities of the Disclosure Committee, that the Disclosure Committee is responsible for:

    - Reviewing in advance the Company's quarterly earnings press releases and related materials (such as earnings conference call scripts) with respect to the adequacy and accuracy of the disclosures included therein;

    - Reviewing transcripts of analyst conference calls and other investor presentations with respect to the accuracy of any disclosures made, advising the Audit Committee of any corrections that the Disclosure Committee determines need to be made, and oversight with respect to the drafting of any required corrective disclosures;

    - Preparing and submitting to the Board a written report whenever any new material disclosure risks are identified concerning developments in the Company's clinical trials and drug approval efforts;

    - Providing a written report to the Audit Committee, at least quarterly, regarding potential or actual material disclosure issues identified; and

    - Providing a report to the Board, at least annually, summarizing its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Research and Development Committee (which was created in the context of the Derivative Actions) shall be amended to provide (among other things) that the Research and Development Committee shall be responsible for: (i) reviewing and evaluating the design of the Company's clinical trials; (ii) tracking and evaluating the progress of all ongoing clinical trials; (iii) tracking the Company's ongoing relationships with any regulatory agency governing the clinical trials, including without limitation, the FDA; and (iv) working in conjunction with the Company's management-level Disclosure Committee and the Audit Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the status of any clinical trials undertaken by the Company, as well as communications with any regulatory agency governing the clinical trials, including without limitation, the FDA. The Research and Development Committee shall ensure that the Audit Committee and the Board are promptly made aware when any issues arising out of a clinical trial are considered material by the Research and Development Committee. The Research and Development Committee shall report at least annually to the Board with respect to its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Audit Committee shall be amended to include the following additional responsibilities:

    - The Audit Committee shall receive quarterly (and more often as warranted) updates from the Chief Financial Officer and/or the Company's management-level Disclosure Committee regarding the efforts of the Disclosure Committee. The Audit Committee shall work in conjunction with the Disclosure Committee and the Research and Development Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the status of any clinical trials undertaken by the Company, as well as interactions with the FDA.

    - The Audit Committee shall receive quarterly (and more often as necessary) updates from the Company's management on its risk management process. The Audit Committee shall report to the Board whenever any material risks relating to the Company's legal and/or regulatory compliance are identified, including with respect to recommendations regarding proposals for mitigating these risks, as well as relevant considerations relating to the Company's public disclosures of these risks.

    - The Audit Committee shall receive reports from and coordinate with the Research and Development Committee regarding the integrity and accuracy of the Company's press releases and regulatory filings with respect to its clinical trials and studies. In the event the Research and Development Committee presents the Audit Committee with information concerning any developments related to a clinical trial that are sufficiently material to trigger a disclosure obligation, the Audit Committee shall assess whether any corrective or other disclosures are required.

    - The Audit Committee shall receive annually a report listing all trades in the Company's securities engaged in by Section 16 officers of the Company.

- The Charter of the Nominating and Corporate Governance Committee shall be amended to provide that the Committee shall meet either in-person or virtually with each prospective new Board member prior to his or her nomination to the Board.

- The Charter of the Compensation and Talent Strategy Committee shall be amended to provide that: (i) in its consideration of compensation recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; (ii) in its consideration of severance arrangements recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; and (iii) the Committee shall consist of at least three (3) members.

- As an initial action item following the Company's commercialization of one or more of its therapeutic product candidates ("commercialization"), in the event the Company does not yet have a Chief Compliance Officer, the Company will appoint a Chief Compliance Officer as soon as is practicable, unless the Audit Committee, in conjunction with input from an outside independent consultant, determines in good faith that it is not in the Company's best interests, taking into account, among other considerations, the regulatory compliance obligations and financial resources of the Company. In the event the Company has not appointed a Chief Compliance Officer within six (6) months of commercialization, the Audit Committee shall provide a report regarding its determinations, the reasons for not appointing a Chief Compliance Officer, and how the duties of a Chief Compliance Officer otherwise will be fulfilled by other existing positions to the Board.

- The Insider Trading Policy shall be amended to incorporate the following revisions, which are reflected in the amended Insider Trading Policy attached hereto as Exhibit 2:

    - The Company shall undertake an annual review reasonably intended to ensure that the Insider Trading Policy remains up-to-date with respect to insider trading laws and regulations.

    - The Company shall obtain annual written certifications from directors, and executive officers indicating that those individuals have read and understood the terms of the Insider Trading Policy.

    - In the next quarterly filing following the approval of a new or amended Rule 10b5-1 plan for any director or executive officer, the Company shall disclose: (1) the name of the plan enrollee; (2) the date the plan was entered into; and (3) the date the plan expires, if applicable.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, during the pendency of any Company-funded open market stock buy-back program, no director or officer subject to reporting obligations under Section 16 of the Exchange Act shall be permitted to sell stock of the Company.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, officers subject to reporting obligations under Section 16 of the Exchange Act shall be prohibited from trading securities of the Company for the period of time beginning no later than the fifteenth (15th) day of the last month of each quarter and ending upon the completion of the second full trading day after the public announcement of earnings each quarter.

    - Any failure to comply with the Insider Trading Policy by any employee of the Company will result in an assessment by the Company concerning appropriate disciplinary action, which may include reimbursement for any fines, fees, or expenses incurred by the Company as a result of any noncompliance with the Insider Trading Policy, cancellation of outstanding stock options, disqualification from performance-based compensation, and employee discipline up to and including termination.

- The Clawback Policy shall be amended to provide the following, which is reflected in the amended Clawback Policy attached hereto as Exhibit 3:

    - Upon any restatement of the Company's financial results, the Board shall oversee an investigation reasonably intended to assess (1) whether any compensation, including in particular any incentive-based compensation (including stock options awarded as compensation), was paid to the Company's CEO, CFO, or any other executive officer on the basis of any misstated financial results; and (2) whether the restatement was caused by fraud or intentional misconduct (as defined below in Exhibit 3) of the CEO, CFO, or any other executive officer.

    - The Company shall disclose in its Compensation Discussion and Analysis a summary of the Board's investigation.

- The Board shall maintain and publish on the Company's website the following policies (as revised, where appropriate) for the entirety of the Compliance Term:

    - Insider Trading Policy

    - Related Person Transactions Policy

    - Clawback Policy

- The Code of Business Conduct and Ethics shall be amended to require that the Company institute mandatory annual employee training concerning applicable policies and codes of conduct, as appropriate given the employee's role within the Company.

- The Board shall maintain the provision in the Corporate Governance Guidelines that requires new directors to participate in the Company's orientation program for new directors.

- The Board shall amend the Corporate Governance Guidelines to require director participation in continuing education for directors, as the Board determines appropriate.

- The Board shall publish the revised Corporate Governance Guidelines and Code of Business Conduct and Ethics on the Company's website and include a link to those documents in the Company's proxy statements.

- The Board shall publish all Board committee charters, as revised, on the Company's website for the at least the duration of the Compliance Term.

- In the event that a final non-appealable judgment is entered against defendant Guyer and/or defendant Patel following summary adjudication or trial, including the conclusion of any and all appeals, in *Micholle v. Ophthotech Corporation, et al.*, Case No. 1:17-cv-00210-VSB-GWG (S.D.N.Y.) (the "Securities Class Action") for violation(s) of federal securities laws in which defendant Guyer and/or defendant Patel is found to have acted willfully in bad faith, Ophthotech shall, to the extent not inconsistent with applicable legal obligations,

including but not limited to the Company's legal obligations to defendants Guyer and Patel contained in the Company's Fourth Amended and Restated Certificate of Incorporation, Paragraph TENTH, pursue sums previously paid pursuant to the Company's advancement and/or indemnification obligations to or for the benefit of the defendant(s) against whom such a final non-appealable judgment is entered.

2. CORPORATE GOVERNANCE ENHANCEMENTS AND OTHER CHANGES ALREADY IMPLEMENTED

- The Derivative Actions were a factor considered by the Company and its Board in connection with modifications it made to its board composition and structure in the period between (1) the filing of such litigation and the transmittal of litigation demands and (2) the parties' agreement in principle in connection with mediation to settle these Derivative Actions. Such modifications include the appointment of new, non-defendant directors to fill vacancies created by director departures.

- Concerns, including as expressed by the derivative plaintiffs in litigation and the demanding shareholders in correspondence and demands, were substantial contributing factors to the following corporate governance measures and enhancements:

    - Adoption of the Clawback Policy

    - Adoption of the Stock Retention and Ownership Guidelines

    - Amendments to the Code of Business Conduct and Ethics

VII. PLAINTIFFS' COUNSEL'S SEPARATELY NEGOTIATED AGREED-TO ATTORNEYS' FEES AND EXPENSES

After negotiating the principal terms of the Settlement, counsel for the Settling Parties, the SLC, and the Individual Defendants' insurers, acting by and through their respective counsel, with the substantial assistance of the Mediator, separately negotiated the attorneys' fees and expenses the Individual Defendants would cause their insurers to pay to Plaintiffs' Counsel based on the substantial benefits conferred upon Ophthotech by the Settlement.

In consideration of the substantial benefits conferred upon Ophthotech as a direct result of the Settlement and the efforts of Plaintiffs and Plaintiffs' Counsel in the Derivative Actions, and subject to Court approval, the Individual Defendants shall cause their insurers to pay Plaintiffs' Counsel attorneys' fees and expenses in the total amount of $2,450,000 (the "Fee and Expense

Amount"). The members of the SLC, in the good faith exercise of their business judgment, have approved the agreed-to Fee and Expense Amount in light of the substantial benefits conferred upon Ophthotech as a result of the Settlement and Plaintiffs' Counsel's efforts in this litigation.

The Settling Parties further stipulated that Plaintiffs' Counsel may apply to the Court for service awards of up to $5,000 for each of the Plaintiffs, only to be paid upon Court approval, and to be paid from the Fee and Expense Amount, in recognition of Plaintiffs' participation and effort in the prosecution of the Derivative Actions.

VIII. SETTLEMENT HEARING

On _____, 2022, at __:___ __.m., the Court will hold the Settlement Hearing at the United States District Court for the Southern District of New York, 40 Foley Square, New York, New York 10007. At the Settlement Hearing, the Court will consider whether the terms of the Settlement are fair, reasonable, and adequate and thus should be finally approved, whether the separately negotiated Fee and Expense Amount and Plaintiffs' service awards should be approved, and whether the Derivative Actions should be dismissed with prejudice pursuant to the Stipulation.

Pending the Court's determination as to final approval of the Settlement, Plaintiffs and all Current Company Stockholders are barred and enjoined from commencing, instituting, filing, intervening in, participating in, receiving any benefit from, or prosecuting any action, including without limitation any derivative action, asserting any of the Released Claims against any of the Released Persons.

IX. RIGHT TO ATTEND SETTLEMENT HEARING

Any current Ophthotech stockholder may, but is not required to, appear in person at the Settlement Hearing. If you want to be heard at the Settlement Hearing, then you must first comply with the procedures for objecting, which are set forth below. The Court has the right to change

the hearing date or time without further notice or to hold it telephonically or via another remote process. Thus, if you are planning to attend the Settlement Hearing, you should confirm the date and time before going to the Court. Current Company Stockholders who have no objection to the Settlement do not need to appear at the Settlement Hearing or take any other action.

X. RIGHT TO OBJECT TO THE PROPOSED DERIVATIVE SETTLEMENT AND PROCEDURES FOR DOING SO

Any current Ophthotech stockholder may appear and show cause, if he, she, or it has any reason why the Settlement of the Derivative Actions should not be approved as fair, reasonable, and adequate, or why a judgment should not be entered thereon, or why the separately negotiated attorneys' fees and expenses should not be approved. You must object in writing, and you may request to be heard at the Settlement Hearing. If you choose to object, then you must follow these procedures.

A. You Must Make Detailed Objections in Writing

Any objections must be presented in writing and must contain the following information:

1. Your name, legal address, and telephone number;

2. The case name and number (*Pacheco v. Guyer*, Case No. 1:18-cv-07999);

3. Proof of being an Ophthotech stockholder as of the Record Date, January 27, 2022.

4. The date(s) you acquired your Ophthotech shares;

5. A statement of each objection being made;

6. Notice of whether you intend to appear at the Settlement Hearing (you are not required to appear); and

7. Copies of any papers you intend to submit to the Court, along with the names of any witness(es) you intend to call to testify at the Settlement Hearing and the subject(s) of their testimony.

The Court may not consider any objection that does not substantially comply with these requirements.

B. You Must Timely Deliver Written Objections to the Court

All written objections and supporting papers must be submitted to the Court either by mailing them to:

Clerk of the Court
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
40 Foley Square
New York, New York 10007

OR by filing them in person at any location of the United States District Court for the Southern District of New York.

YOUR WRITTEN OBJECTIONS MUST BE POSTMARKED OR ON FILE WITH THE CLERK OF THE COURT NO LATER THAN _____.

Unless the Court orders otherwise, your objection will not be considered unless it is timely filed with the Court.

Your written objection must also be mailed to:

Plaintiffs' Counsel:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5040 Shoreham Place
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

Defendants' Counsel:

Michael G. Bongiorno
Jeremy T. Adler
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Counsel for Defendants and Nominal Defendant

Jordan D. Hershman
MORGAN, LEWIS & BOCKIUS LLP
One Federal Street
Boston, MA 02110

Counsel for Defendants David R. Guyer and Samir C. Patel

Any Person or entity who fails to object or otherwise request to be heard in the manner prescribed above will be deemed to have waived the right to object to any aspect of the Settlement as incorporated in the Stipulation or otherwise to be heard (including the right to appeal) and will be forever barred from raising such objection or request to be heard in this or any other action or proceeding, and, unless otherwise ordered by the Court, shall be bound by the Judgment to be entered and the releases to be given.

XI. RELEASES

Upon the Effective Date, the Releasing Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged with prejudice and on the merits, to the fullest extent permitted by law, each and all of the Released Persons from and with respect to each and all of the Released Claims (including Unknown Claims), and will be forever barred and enjoined from commencing, instituting, or prosecuting any action or proceeding, in any forum, asserting any of the Released Claims against any of the Released Persons, including but not limited to any and all

claims arising out of, relating to, or in connection with the defense, settlement, or resolution of the Derivative Actions against the Released Persons.

Upon the Effective Date, each of the Defendants shall be deemed to have fully, finally, and forever released, relinquished, and discharged Plaintiffs and Plaintiffs' Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection with the institution, prosecution, assertion, settlement, or resolution of the Derivative Actions or the Released Claims.

Upon the Effective Date, each of the Settling Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged the members of the SLC and SLC Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection with the investigation, settlement, or resolution of the Derivative Actions or the Released Claims.

"Released Claims" means any and all manner of claims, demands, rights, liabilities, losses, obligations, duties, damages, costs, debts, expenses, interest, penalties, sanctions, fees, attorneys' fees, actions, potential actions, causes of action, suits, agreements, judgments, decrees, matters, issues and controversies of any kind, nature or description whatsoever, whether known or unknown, disclosed or undisclosed, accrued or unaccrued, apparent or not apparent, foreseen or unforeseen, matured or not matured, suspected or unsuspected, liquidated or not liquidated, fixed or contingent, including without limitation Unknown Claims (as defined in paragraph 1.33 of the Stipulation), whether based on state, local, foreign, federal, statutory, regulatory, common or other law or rule, brought or that could be brought by Ophthotech or derivatively on behalf of Ophthotech that arise out of or relate to: (i) the allegations asserted in the Derivative Actions; or (ii) the Settlement, except for any claims to enforce the Settlement. Excluded from the term "Released Claims" are all claims asserted in the Securities Action.

"Released Persons" means collectively, Ophthotech, the Individual Defendants, and their Related Persons. "Related Persons" means: (i) with regard to each Individual Defendant, the Individual Defendants' spouses, marital communities, immediate family members, heirs, executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns or any other entity in which any Individual Defendant has a controlling interest, and each and all of their respective past and present officers, directors, employees, agents, affiliates, parents, subsidiaries, divisions, attorneys, accountants, auditors, advisors, insurers, co-insurers, re-insurers, heirs, executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns; and (ii) with regard to Ophthotech, all past or present agents, officers, directors, attorneys, accountants, auditors, advisors, insurers, co-insurers, reinsurers, partners, controlling shareholders, joint venturers, related or affiliated entities, advisors, employees, affiliates, predecessors, successors, parents, subsidiaries, insurers, and assigns for Ophthotech.

"Releasing Parties" means Plaintiffs, all other Current Company Stockholders, Plaintiffs' Counsel, and Ophthotech

XII. HOW TO OBTAIN ADDITIONAL INFORMATION

This Notice summarizes the Stipulation. It is not a complete statement of the events of the Derivative Actions or the Settlement contained in the Stipulation.

You may inspect the Stipulation and other papers in the Derivative Actions at the United States District Court Clerk's office at any time during regular business hours of each business day. The Clerk's office is located at the United States District Court for the Southern District of New York, 40 Foley Square, New York, New York 10007. However, you may visit the Company's website to inspect the Stipulation or contact counsel listed below. The Clerk's office will not mail

copies to you. You may also view and download the Stipulation at _____.

If you have any questions about matters in this Notice, you may contact:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5040 Shoreham Place
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

PLEASE DO NOT CALL, WRITE, OR OTHERWISE DIRECT QUESTIONS TO EITHER THE COURT OR THE CLERK'S OFFICE.

DATED: _____, 2022

BY ORDER OF THE COURT
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EXHIBIT B-2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB **SUMMARY NOTICE OF PENDENCY AND PROPOSED SETTLEMENT OF SHAREHOLDER DERIVATIVE ACTIONS**

TO: ALL RECORD HOLDERS AND BENEFICIAL OWNERS OF THE COMMON STOCK OF IVERIC BIO, INC. F/K/A/ OPHTHOTECH CORPORATION ("OPHTHOTECH" OR THE "COMPANY") AS OF JANUARY 27, 2022 (THE "RECORD DATE"), EXCLUDING DEFENDANTS AND ANY ENTITY IN WHICH THEY HAVE A CONTROLLING INTEREST AND OFFICERS AND DIRECTORS OF THE COMPANY AND THEIR LEGAL REPRESENTATIVES, HEIRS, SUCCESSORS, OR ASSIGNS

PLEASE TAKE NOTICE that the shareholder Derivative Actions[1] are being settled on the terms set forth in a Stipulation of Settlement, dated January 27, 2022 (the "Stipulation" or "Settlement"). This notice should be read in conjunction with, and is qualified in its entirety by reference to, the text of the Stipulation, which has been filed with the United States District Court for the Southern District of New York. A link to the text of the Stipulation and the full-length Notice of Pendency and Proposed Settlement of Shareholder Derivative Actions may be found on the Company's website at the Investor Relations page at _____. All capitalized terms herein have the same meanings as set forth in the Stipulation.

Under the terms of the Stipulation, as part of the proposed Settlement, Ophthotech has agreed to adopt within sixty (60) days of Court's final approval of the Settlement certain corporate governance measures that serve as the basis for the resolution of the claims asserted in the Derivative Actions. The Company has agreed to maintain those governance measures for a period of no less than four (4) years.[2] The corporate governance measures are detailed in their entirety in Exhibit A to the Stipulation and the exhibits attached thereto.

---

[1] The Settlement also resolves all claims asserted in a second action styled *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup. Ct. N.Y. Cnty.) and in a litigation demand made by shareholder Richard Waksman (together the "Derivative Actions"). Plaintiffs are Luis Pacheco, Brian Ferber, Angel Ham, and Richard Waksman.

[2] The corporate governance measures required by the Settlement may be eliminated or modified to the extent required by applicable law, regulation, or fiduciary duty, or upon a Change in Control Event, in which case all duties and obligations to maintain the Corporate Governance Measures

The Special Litigation Committee ("SLC"), a committee of outside non-defendant directors established to investigate and take and direct any and all actions on behalf of the Company with respect to the Derivative Actions, participated in the negotiation of the Settlement, and reviewed the proposed derivative settlement terms. The members of the SLC, acting on the Company's behalf, have unanimously approved a resolution reflecting their determination, in an exercise of their business judgment, that: (a) Plaintiffs' litigation and settlement efforts in the Derivative Actions were a material and contributing factor in the Board's agreement to adopt, implement, and maintain the Corporate Governance Measures for the agreed term; (b) the Corporate Governance Measures reflected in Exhibit A to the Stipulation confer substantial benefits on the Company and its stockholders; and (c) the Settlement is fair, reasonable and in the best interests of the Company and its stockholders.

After negotiating the principal terms of the Settlement, counsel for the Settling Parties, the SLC, and Defendants' insurers, acting by and through their respective counsel, and with the substantial assistance of the Mediator, separately negotiated the attorneys' fees and expenses the Individual Defendants would cause their insurers to pay to Plaintiffs' Counsel based on the substantial benefits conferred upon Ophthotech by the Settlement. In consideration of the substantial benefits conferred upon Ophthotech as a direct result of the Settlement and the efforts

---

shall become subject to the good faith exercise of the succeeding board's or controlling group's or entity's business judgment. The Corporate Governance Measures may be amended or eliminated if a majority of the independent members of the Board determine in a good faith exercise of their business judgment that the implementation or maintenance of the Corporate Governance Measure(s) would be contrary to applicable laws or regulations, including the Board's fiduciary duties. In such event, the independent directors, to the extent their fiduciary obligations allow based upon their good faith exercise of business judgment, shall adopt an amended or substitute reform that addresses the same goals, purposes and/or functions of the original Corporate Governance Measure(s) as soon as practicable. Any changes made pursuant to the above shall be published in the Company's next regular quarterly filing with the SEC.

of Plaintiffs and Plaintiffs' Counsel in the Derivative Actions, and subject to Court approval, the Individual Defendants shall cause their insurers to pay Plaintiffs' Counsel attorneys' fees and expenses in the total amount of $2,450,000 (the "Fee and Expense Amount"). The members of the SLC, in the good faith exercise of their business judgment, have approved the agreed-to Fee and Expense Amount in light of the substantial benefits conferred upon Ophthotech as a result of the Settlement and Plaintiffs' Counsel's efforts in this litigation.[3]

IF YOU WERE A RECORD OR BENEFICIAL OWNER OF OPHTHOTECH COMMON STOCK AS OF JANUARY 27, 2022, PLEASE READ THIS NOTICE CAREFULLY AND IN ITS ENTIRETY AS YOUR RIGHTS MAY BE AFFECTED BY PROCEEDINGS IN THE ABOVE-REFERENCED LITIGATION.

On _____, 2022, at __:___ __.m., a hearing (the "Settlement Hearing") will be held at the United States District Court for the Southern District of New York, 40 Foley Square, New York, New York 10007, before the Honorable Vernon S. Broderick to determine: (i) whether the terms of the proposed Settlement, including the separately negotiated attorneys' fees and expenses and the service awards, should be approved as fair, reasonable, and adequate; and (2) whether the Derivative Actions should be dismissed on the merits and with prejudice on the terms set forth in the Stipulation.

Any Ophthotech stockholder that objects to the Settlement shall have a right to appear and to be heard at the Settlement Hearing, provided that he, she, or it was a stockholder of record or beneficial owner as of January 27, 2022. Any Ophthotech stockholder who satisfies this

[3] The Settling Parties further stipulated that Plaintiffs' Counsel may apply to the Court for service awards of up to $5,000 for each of the Plaintiffs, only to be paid upon Court approval, and to be paid from the Fee and Expense Amount, in recognition of Plaintiffs' participation and effort in the prosecution of the Derivative Actions.

requirement may enter an appearance through counsel of such stockholder's own choosing and at such stockholder's own expense, or may appear on their own. However, no stockholder of Ophthotech shall be heard at the Settlement Hearing unless, no later than _____, 2022, such stockholder has filed with the Court and counsel for the parties, a written notice of objection containing the following information:

1. Your name, legal address, and telephone number;

2. The case name and number (*Pacheco v. Guyer*, Case No. 1:18-cv-07999);

3. Proof of being an Ophthotech stockholder as of the Record Date, January 27, 2022.

4. The date(s) you acquired your Ophthotech shares;

5. A statement of each objection being made;

6. Notice of whether you intend to appear at the Settlement Hearing (you are not required to appear); and

7. Copies of any papers you intend to submit, along with the names of any witness(es) you intend to call to testify at the Settlement Hearing and the subject(s) of their testimony.

Only stockholders who have filed and delivered valid and timely written notices of objection will be entitled to be heard at the Settlement Hearing unless the Court orders otherwise.

If you wish to object to the proposed Settlement, you must file the written objection described above with the Court and counsel for the parties on or before _____, 2022.

Any Person who does not make his, her, or its objection in the manner provided herein shall be deemed to have waived such objection and shall be forever foreclosed from making any objection to the fairness, reasonableness, or adequacy of the Settlement as incorporated in the

Stipulation and/or to the separately negotiated attorneys' fees and expenses to Plaintiffs' Counsel, unless otherwise ordered by the Court, but shall otherwise be bound by the Judgment to be entered and the releases to be given.

If you have any questions about matters in this Notice, you may contact:

Plaintiffs' Counsel:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5040 Shoreham Place
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

Defendants' Counsel:

Michael G. Bongiorno
Jeremy T. Adler
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Counsel for Defendants and Nominal Defendant

Jordan D. Hershman
MORGAN, LEWIS & BOCKIUS LLP
One Federal Street
Boston, MA 02110

Counsel for Defendants David R. Guyer and Samir C. Patel

PLEASE DO NOT CONTACT THE COURT REGARDING THIS NOTICE.

DATED: _____, 2022

BY ORDER OF THE COURT
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB **[PROPOSED] ORDER AND FINAL JUDGMENT APPROVING DERIVATIVE SETTLEMENT AND ORDER OF DISMISSAL WITH PREJUDICE**

This matter came before the Court for hearing pursuant to the Order of this Court, dated _____, 2022 ("Order"), on Plaintiff's motion for final approval of the settlement ("Settlement") set forth in the Stipulation of Settlement, dated January 27, 2022 (the "Stipulation"). Due and adequate notice having been given of the Settlement as required in said Order, and the Court having considered all papers filed and proceedings had herein, and otherwise being fully informed in the premises and good cause appearing therefor, IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Order and Final Judgment incorporates by reference the definitions in the Stipulation, and all capitalized terms used herein shall have the same meanings as set forth in the Stipulation (in addition to those capitalized terms defined therein).

2. This Court has jurisdiction over the subject matter of this litigation, including all matters necessary to effectuate the Settlement, and over all parties, including, but not limited to, the Plaintiffs, IVERIC bio, Inc. f/k/a/ Ophthotech Corporation ("Ophthotech"), Current Company Stockholders, and the Defendants.

3. The Court finds that the notice provided to Ophthotech stockholders was the best notice practicable under the circumstances of these proceedings and of the matters set forth therein, including the Settlement set forth in the Stipulation, to all Persons entitled to such notice. The notice fully satisfied the requirements of Federal Rule of Civil Procedure 23.1 and due process.

4. The Federal Derivative Action, and all claims contained therein, as well as all of the Released Claims, are dismissed with prejudice. As among Plaintiffs, Defendants, and Ophthotech, the parties are to bear their own costs, except as otherwise provided herein and/or in the Stipulation.

5. The Court finds that the terms of the Stipulation and Settlement are fair, reasonable, and adequate as to each of the Settling Parties, and hereby finally approves the Stipulation and Settlement in all respects, and orders the Settling Parties to perform its terms to the extent the Settling Parties have not already done so.

6. Upon the Effective Date, as defined in paragraph 6.1 of the Stipulation, the Plaintiffs (acting on their own behalf and derivatively on behalf of Ophthotech and its stockholders), all other stockholders of Ophthotech, and Ophthotech, for good and sufficient consideration, the receipt and adequacy of which are hereby acknowledged, shall be deemed to have, and by operation of law and of this Judgment shall have, fully, finally, and forever compromised, settled, released, resolved, relinquished, waived, and discharged and dismissed with prejudice each and every one of the Released Claims against the Released Persons, and shall be forever barred and enjoined from commencing, instituting or prosecuting any of the Released Claims against any of the Released Persons. Nothing herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of the Stipulation.

7. Upon the Effective Date, as defined in paragraph 6.1 of the Stipulation, each of the Released Persons, for good and sufficient consideration, the receipt and adequacy of which are hereby acknowledged, shall be deemed to have, and by operation of law and of this Judgment shall have, fully, finally, and forever compromised, settled, released, resolved, relinquished, waived, and discharged each and all of the Plaintiffs and Plaintiffs' Counsel and all Ophthotech stockholders (solely in their capacity as Ophthotech stockholders) from all claims (including Unknown Claims) arising out of, relating to, or in connection with the institution, prosecution, assertion, settlement or resolution of the Derivative Actions or the Released Claims. Nothing

herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of the Stipulation.

8. Upon the Effective Date, as defined in paragraph 6.1 of the Stipulation, each of the Settling Parties, for good and sufficient consideration, the receipt and adequacy of which are hereby acknowledged, shall be deemed to have, and by operation of law and of this Judgment shall have, fully, finally, and forever compromised, settled, released, resolved, relinquished, waived, and discharged the members of the SLC and SLC Counsel from all claims (including Unknown Claims) arising out of, relating to, or in connection with the investigation, settlement, or resolution of the Derivative Actions or the Released Claims. Nothing herein shall in any way impair or restrict the rights of any Settling Party to enforce the terms of the Stipulation.

9. The Court hereby approves the agreed Fee and Expense Amount in accordance with the Stipulation and finds that such fee is fair and reasonable in light of the substantial benefit conferred upon Ophthotech by the Settlement.

10. The Court hereby approves the service awards for the Plaintiffs in accordance with the Stipulation and finds that such awards are fair and reasonable in light of the substantial benefit conferred upon Ophthotech by the Settlement.

11. Neither the Stipulation nor the Settlement, including the Exhibits attached thereto, nor any act performed or document executed pursuant to or in furtherance of the Stipulation or the Settlement: (a) is or may be deemed to be or may be offered, attempted to be offered or used in any way as a concession, admission or evidence of the validity of any Released Claims, or of any fault, wrongdoing, or liability of the Released Persons or Ophthotech or (b) is or may be deemed to be or may be used as a presumption, admission, or evidence of, any liability, fault or omission of any of the Released Persons or Ophthotech in any civil, criminal, administrative or other

proceeding in any court, administrative agency, tribunal, or other forum. Neither the Stipulation nor the Settlement shall be admissible in any proceeding for any purpose, except to enforce the terms of the Settlement, and except that the Released Persons may file or use the Stipulation or this Order and Final Judgment in any action that may be brought against them in order to support a defense or counterclaim based on principles of *res judicata*, collateral estoppel, full faith and credit, release, good faith settlement, standing, judgment bar or reduction, or any other theory of claim preclusion or issue preclusion or similar defense or counterclaim.

12. During the course of the Derivative Actions, the parties and their respective counsel at all times complied with the requirements of Federal Rule of Civil Procedure 11, and all other similar laws relating to the institution, prosecution, defense of, or settlement of the Derivative Actions.

13. Without affecting the finality of this Order and Final Judgment in any way, this Court hereby retains continuing and exclusive jurisdiction over the instant Action and the parties to the Stipulation to enter any further orders as may be necessary to effectuate, implement, and enforce the Stipulation and the Settlement provided for therein and the provisions of this Order and Final Judgment.

14. This Order and Final Judgment is a final and appealable resolution as to all claims, and the Court directs immediate entry of this Order and Final Judgment forthwith by the Clerk in accordance with Rule 58 of the Federal Rules of Civil Procedure, dismissing the Federal Derivative Action with prejudice.

15. For the reasons stated in, and pursuant to the terms set forth in this Order and Final Judgment, Plaintiff's motion for final approval of derivative settlement is granted; accordingly, this case is closed.

DATED: _____

_____
HONORABLE VERNON S. BRODERICK
UNITED STATES DISTRICT JUDGE

1551933

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LUIS PACHECO, Derivatively on Behalf of OPHTHOTECH CORPORATION, Plaintiff, v. DAVID R. GUYER, GLENN P. SBLENDORIO, DAVID E. REDLICK, THOMAS DYRBERG, AXEL BOLTE, MICHAEL J. ROSS, SAMIR C. PATEL, and NICHOLAS GALAKATOS, Defendants, -and- OPHTHOTECH CORPORATION, a Delaware corporation, Nominal Defendant.	Case No. 1:18-cv-07999-VSB **NOTICE OF PENDENCY AND PROPOSED SETTLEMENT OF SHAREHOLDER DERIVATIVE ACTIONS**

TO: ALL RECORD HOLDERS AND BENEFICIAL OWNERS OF THE COMMON STOCK OF IVERIC BIO, INC. F/K/A/ OPHTHOTECH CORPORATION ("OPHTHOTECH" OR THE "COMPANY") AS OF JANUARY 27, 2022 (THE "RECORD DATE"), EXCLUDING DEFENDANTS AND ANY ENTITY IN WHICH THEY HAVE A CONTROLLING INTEREST AND OFFICERS AND DIRECTORS OF THE COMPANY AND THEIR LEGAL REPRESENTATIVES, HEIRS, SUCCESSORS, OR ASSIGNS.

PLEASE READ THIS NOTICE CAREFULLY AND IN ITS ENTIRETY. THIS NOTICE RELATES TO A PROPOSED SETTLEMENT AND DISMISSAL OF THE ABOVE-CAPTIONED DERIVATIVE ACTION AND OTHER SHAREHOLDER DERIVATIVE MATTERS AND CONTAINS IMPORTANT INFORMATION REGARDING YOUR RIGHTS. YOUR RIGHTS MAY BE AFFECTED BY THESE LEGAL PROCEEDINGS. IF THE COURT APPROVES THE SETTLEMENT, YOU WILL BE FOREVER BARRED FROM CONTESTING THE APPROVAL OF THE PROPOSED SETTLEMENT AND FROM PURSUING THE RELEASED CLAIMS.

IF YOU HOLD OPHTHOTECH COMMON STOCK FOR THE BENEFIT OF ANOTHER, PLEASE PROMPTLY TRANSMIT THIS DOCUMENT TO SUCH BENEFICIAL OWNER.

PLEASE NOTE THAT THERE IS NO CLAIMS PROCESS AND NO INDIVIDUAL STOCKHOLDER HAS THE RIGHT TO BE COMPENSATED AS A RESULT OF THE SETTLEMENT DESCRIBED BELOW.

A federal court authorized this Notice. This is not a solicitation from a lawyer.

I. WHY THE COMPANY HAS ISSUED THIS NOTICE

Notice is hereby provided to you of the proposed settlement (the "Settlement") of this stockholder derivative litigation and related matters. This Notice is provided by Order of the United States District Court for the Southern District of New York (the "Court"). It is not an expression of any opinion by the Court with respect to the truth of the allegations in the litigation or merits of the claims or defenses asserted by or against any party. It is solely to notify you of the terms of the proposed Settlement and your rights related thereto. The terms of the proposed Settlement are set forth in a written Stipulation of Settlement dated January 27, 2022 ("Stipulation").[1] A link to the Form 8-K filed with the SEC containing the text of the Stipulation may be found on Ophthotech's website at the Investor Relations page at https://investors.ivericbio.com/derivative-settlement.

Your rights may be affected by the settlement of the following matters, including without limitation all related stockholder demands: *Pacheco v. Guyer, et al.*, Case No. 1:18-cv-07999-VSB (S.D.N.Y.); *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 (N.Y. Sup. Ct. N.Y. Cnty.); and the litigation demand made by shareholder Richard Waksman (together the "Derivative Actions"). Plaintiffs Luis Pacheco, Brian Ferber, Angel Ham and Richard Waksman ("Plaintiffs") (on behalf of themselves and derivatively on behalf of Ophthotech); individual defendants David R. Guyer, Glenn P. Sblendorio, David E. Redlick, Thomas Dyrberg, Axel Bolte, Michael J. Ross,

[1] Capitalized terms not otherwise defined shall have the same meanings as set forth in the Stipulation.

Samir C. Patel, Nicholas Galakatos; and nominal defendant Ophthotech (the "Defendants") (Plaintiffs and Defendants collectively, the "Settling Parties") have agreed upon terms to settle the above-referenced litigation and have signed the Stipulation setting forth those settlement terms.

On January 20, 2023, at 4:00 p.m., the Court will hold a hearing (the "Settlement Hearing") in the Federal Derivative Action. The purpose of the Settlement Hearing is to determine: (i) whether the Settlement is fair, reasonable, and adequate, including the separately negotiated amount of attorneys' fees and expenses for Plaintiffs' Counsel and the case contribution awards for the Plaintiffs, and should be finally approved; (ii) whether a final judgment should be entered and the Federal Derivative Action dismissed with prejudice pursuant to the Stipulation; and (iii) such other matters as may be necessary and proper under the circumstances.

II. OPHTHOTECH DERIVATIVE LITIGATION

A. The Federal Derivative Action

1. Federal Plaintiff Commences This Derivative Litigation

On August 31, 2018, Federal Plaintiff filed a Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment (the "Complaint") against individual defendants David R. Guyer, Glenn P. Sblendorio, David E. Redlick, Thomas Dyrberg, Axel Bolte, Michael J. Ross, Samir C. Patel, and Nicholas Galakatos (the "Individual Defendants"), on behalf of nominal defendant Ophthotech, captioned *Pacheco v. Guyer, et al*., C.A. No. 1:18-cv-07999-VSB (the "Federal Derivative Action").

Federal Plaintiff alleged that the Individual Defendants made and permitted the issuance of public statements that omitted material facts concerning: (i) the average lesion size and average visual acuity of patients in the control group for the Phase 2b trial for the Company's lead drug candidate, Fovista, which allegedly had the effect of overstating the drug's efficacy; and (ii)

changes made to the patient inclusion and exclusion criteria for the Fovista Phase 3 trials compared to the prior Phase 2b trial that allegedly adversely impacted the potential for replicating the positive results of the Phase 2b trial. Federal Plaintiff further alleged that the Individual Defendants' misstatements artificially inflated the Company's stock price, and that certain of the Individual Defendants sold their personally held shares of Ophthotech stock at those inflated prices.

Federal Plaintiff did not make a demand on Ophthotech's Board of Directors (the "Board") prior to filing suit and, instead, alleged that demand was excused as futile because there was reason to doubt (i) the disinterestedness of a majority of the Board members, based on the substantial threat of liability they faced; and (ii) the independence of a majority of the Board members, based on various business and financial entanglements.

B. The Court Denies the Defendants' Motion to Dismiss

On December 14, 2018, the Defendants filed a Motion to Dismiss the Verified Stockholder Derivative Complaint (the "Motion to Dismiss") pursuant to Federal Rule of Civil Procedure 23.1, arguing that Federal Plaintiff had failed to adequately allege that a pre-suit demand on the Board would have been futile. After the full briefing of the Motion to Dismiss, on September 19, 2019, the Court denied the Motion to Dismiss.

C. The Board Forms a Special Litigation Committee

In response to the denial of the Motion to Dismiss, on October 15, 2019, Ophthotech's Board established a Special Litigation Committee ("SLC"). Pursuant to a resolution of the Board, the SLC was "fully empowered to take and direct any and all actions on behalf of the Company with respect to [the Federal Derivative Action] and any stockholder derivative litigation [thereafter] filed that raises substantially similar allegations … or otherwise with respect to the allegations therein, including but not limited to investigating and making determinations

concerning or related to claims and allegations of [the Federal Derivative Action], determining whether the pursuit of the [Federal Derivative Action] is in the Company's best interests, causing the Company to pursue claims, causing the Company to seek the dismissal of claims, and seeking any form of relief or action by the Court with respect to the [Federal Derivative Action]."

D. The Parties Agree to Terms on Discovery and a Temporary Stay

Following extensive negotiations, the parties agreed on terms for (i) discovery; and (ii) a temporary stay in order to permit the SLC to conduct its investigation. Specifically, Defendants and the SLC, as appropriate and subject to the terms of the parties' stipulation, agreed to produce to Federal Plaintiff: (i) any final written SLC investigation report or presentation, if any, and any documents identified or referenced therein; (ii) in connection with such final report, if any, other SLC-related documents, including, *inter alia*, documents concerning the formation and independence of the SLC, minutes of relevant meetings of the Board and the SLC, and correspondence between SLC members and other members of the Board (hereinafter, the "SLC-related documents"); (iii) copies of all documents and written responses to discovery requests produced to the plaintiff in *Micholle v. Ophthotech Corporation, et al*., C.A. No. 1:17-cv-00210-VSB-GWG (the "Securities Action") in the form and manner in which such documents were produced to the Securities Action plaintiff; (iv) all written agreements regarding the scope of discovery to be produced by defendants in the Securities Action; and (v) all deposition transcripts generated in the Securities Action.

E. Discovery and Information-Gathering

Between June 2020 and April 2021, Ophthotech produced to Federal Plaintiff more than 100,000 documents constituting more than 4.2 million pages of material, which included transcripts of the depositions of percipient witnesses taken in the related Securities Class Action.

Federal Plaintiff's Counsel attest that they used search terms and custodial information to identify and compile, and then reviewed and evaluated, critical non-public documents and deposition testimony produced by Ophthotech concerning the allegations underlying this litigation.

On April 27, 2021, Federal Plaintiff's Counsel participated in a meeting with counsel for the SLC. Federal Plaintiff's Counsel made a presentation to SLC Counsel that addressed, among other things, (i) the factual allegations, the legal theories for recovery, and the damages alleged to have been suffered by the Company; (ii) corporate governance and other changes that had been made at the Company since the commencement of the Federal Derivative Action; and (iii) potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing. Federal Plaintiff's Counsel and SLC Counsel also discussed the status of the SLC's investigation and next steps, including the possibility of engaging in mediation to explore a potential resolution of the matter.

F. The Litigation Demands

1. The Waksman Demand

On June 22, 2018, Waksman made a demand for the inspection of documents of Ophthotech under 8 Del. C. §220 seeking documents concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "220 Demand"). In response to the 220 Demand, Ophthotech and counsel for Waksman negotiated and entered into a confidentiality agreement. In late October of 2018, Ophthotech provided approximately 2,200 pages of documents to Waksman and his counsel.

On January 23, 2019, subsequent to reviewing the documents, Waksman made a litigation demand on the Board, requesting that it take action to remedy breaches of fiduciary duties by the Individual Defendants in connection with alleged false and misleading statements concerning

Fovista and insider selling by defendants Patel, Guyer, Galakatos, and Sblendorio (the "Waksman Demand"). On March 7, 2019, counsel for Waksman was informed that the Board had formed a demand review committee (the "Demand Review Committee"). Subsequent to the making of the Waksman Demand, counsel for Waksman kept in regular contact with counsel for the Demand Review Committee and SLC concerning the Board's investigations and eventually settlement talks.

2. The Ferber/Ham Demand

On October 12, 2018, Ferber and Ham made a litigation demand upon the Board concerning Fovista's clinical trials and the sale of Ophthotech stock by certain insiders (the "Litigation Demand"). In response to the Litigation Demand, counsel for Ophthotech and counsel for Ferber and Ham exchanged correspondence. On November 30, 2018, counsel for the Company informed Ferber and Ham that the Board had formed the Demand Review Committee to examine the Litigation Demand. Later, that committee's membership was expanded to include Ophthotech director Adrienne Graves, and the SLC was appointed (as discussed above). Counsel for Ferber and Ham also requested that the Company obtain agreements tolling the statute of limitations from the individual defendants named in this Litigation Demand. The Company executed tolling agreements with the individuals. Thereafter, counsel for Ferber and Ham requested action by the SLC and a production of documents as to the investigation. Ferber and Ham subsequently filed an alleged demand-refused action in Supreme Court, New York County, captioned *Ferber, et al. v. Bolte, et al.*, Index No. 154462/2021 on March 6, 2021 (the "State Derivative Action").

Thereafter, counsel for Ferber and Ham and counsel for the Defendants agreed to enter into a temporary stay of the State Derivative Action while the parties pursued global settlement talks. In addition, Ferber and Ham and counsel for the Defendants entered into a stipulation in

which the SLC agreed to produce to counsel for Ferber and Ham the SLC-related documents in accordance with the process provided for in connection with the Federal Derivative Action.

3. Settlement Efforts

On June 21, 2021, the Settling Parties and the SLC participated in an all-day mediation session with the Honorable Layn R. Phillips (Fmr.) and Niki Mendoza, nationally recognized mediators with extensive experience mediating complex stockholder disputes similar to the Derivative Actions, and both of Phillips ADR (the "Mediator"). The Settling Parties and the SLC made substantial progress at the mediation but were unable to resolve the Derivative Actions that day.

Over the course of the next month, the parties continued to engage in arm's-length negotiations regarding the terms of a potential settlement, including, in particular, corporate governance measures at Ophthotech that could form the basis for a settlement. These post-mediation negotiations were conducted via written and telephonic communications, with the continued oversight of the Mediator. The Settling Parties ultimately reached an agreement in principle on the material substantive terms of the Settlement, including the Corporate Governance Measures.

Thereafter, with the substantial involvement of the Mediator, the Settling Parties commenced negotiations regarding the attorneys' fees and expenses to be paid to Plaintiffs' Counsel. Despite their good faith efforts, the Settling Parties were unable to reach an agreement on an appropriate amount of attorneys' fees on their own. Accordingly, on September 1, 2021, the Mediator issued a mediator's recommendation for attorneys' fees and expenses in the amount of $2,450,000, to be paid to Plaintiffs' Counsel by the Individual Defendants' insurer(s) (the "Fee

and Expense Amount"). The Settling Parties agreed to the mediator's recommendation regarding the Fee and Expense Amount on September 3, 2021.

III. PLAINTIFFS' CLAIMS AND THE BENEFITS OF SETTLEMENT

Plaintiffs believe that the Derivative Actions have substantial merit, and Plaintiffs' entry into the Stipulation and Settlement is not intended to be and shall not be construed as an admission or concession concerning the relative strength or merit of the claims alleged in the Derivative Actions. However, Plaintiffs and Plaintiffs' Counsel recognize and acknowledge the significant risk, expense, and length of continued proceedings necessary to prosecute the Derivative Actions against the Individual Defendants through trial and possible appeals. Plaintiffs' Counsel also have taken into account the uncertain outcome and the risk of any litigation, especially in complex cases such as the Derivative Actions, as well as the difficulties and delays inherent in such litigation. Plaintiffs' Counsel are also mindful of the inherent problems of prevailing in the face of a potential motion to terminate by the SLC that was appointed by the Board here, the possible defenses to the claims brought in the Derivative Actions, and the difficulty of prevailing at trial in shareholder derivative litigation, generally.

Plaintiffs' Counsel have conducted extensive investigation and analysis, including, *inter alia*: (i) reviewing the voluminous non-public documents produced in the course of this litigation, including the discovery generated in the related Securities Action and produced to Federal Plaintiff; (ii) reviewing Ophthotech's press releases, public statements, U.S. Securities and Exchange Commission ("SEC") filings, and securities analysts' reports and advisories about the Company; (iii) reviewing related media reports about the Company; (iv) researching applicable law with respect to the claims alleged in the Derivative Actions and potential defenses thereto; (v) preparing and filing derivative complaints; (vi) preparing and sending inspection and litigation

demands; (vii) conducting damages analyses; (viii) evaluating the merits of, and the defendants' potential liability in connection with, the Securities Action; (ix) participating in a formal meeting and making a presentation to SLC Counsel regarding the factual allegations, the legal theories for recovery, the damages alleged to have been suffered by the Company, corporate governance and other changes that had been made at the Company, and potential additional corporate governance measures that could help prevent a recurrence of the alleged wrongdoing; (x) reviewing the Company's existing corporate governance policies and preparing comprehensive yet targeted settlement demands detailing proposed corporate governance measures to strengthen the Company's governance; (xi) participating in extensive settlement discussions, including an all-day mediation and continued follow-up communications with SLC Counsel and Defendants' Counsel and the Mediator; and (xii) negotiating the Stipulation and the exhibits thereto.

Based on Plaintiffs' Counsel's thorough review and analysis of the relevant facts, allegations, defenses, and controlling legal principles, Plaintiffs' Counsel believe that the Settlement set forth in the Stipulation is fair, reasonable, and adequate, and confers substantial benefits upon Ophthotech. Based upon Plaintiffs' Counsel's evaluation, Plaintiffs have determined that the Settlement is in the best interests of Ophthotech and have agreed to settle the Derivative Actions upon the terms and subject to the conditions set forth herein.

IV. DEFENDANTS' DENIALS OF WRONGDOING AND LIABILITY

Defendants have denied and continue to deny each and all of the claims and contentions alleged by Plaintiffs in the Derivative Actions, and the Individual Defendants have expressly denied and continue to deny all charges of wrongdoing or liability against them arising out of any of the conduct, statements, acts, or omissions alleged, or that could have been alleged, in the Derivative Actions. Defendants have also taken into account the uncertainty and risks inherent in

any litigation, especially in complex cases like the Derivative Actions. Defendants have, therefore, determined that it is in the best interests of Ophthotech for the Derivative Actions to be settled in the manner and upon the terms and conditions set forth in the Stipulation.

Neither the Stipulation, nor any of its terms or provisions, nor entry of the Judgment, nor any document or exhibit referenced by or attached to the Stipulation, nor any action taken to carry out the Stipulation, is, may be construed as, or may be used as evidence of the validity of any of the Released Claims or as an admission by or against the Individual Defendants of any fault, wrongdoing, or concession of liability whatsoever.

V. INDEPENDENT DIRECTOR APPROVAL

The members of the SLC, acting on behalf of the Company, have unanimously approved a resolution reflecting their determination, in an exercise of their business judgment, that: (a) Plaintiffs' litigation and settlement efforts in the Derivative Actions were a material and contributing factor in the Board's agreement to adopt, implement, and maintain the Corporate Governance Measures for the agreed term; (b) the Corporate Governance Measures reflected in **Exhibit A** to the Stipulation confer substantial benefits on the Company and its stockholders; and (c) the Settlement is fair, reasonable and in the best interests of the Company and its stockholders.

VI. TERMS OF THE PROPOSED DERIVATIVE SETTLEMENT

The principal terms, conditions, and other matters that are part of the Settlement, which is subject to approval by the Court, are summarized below. This summary should be read in conjunction with, and is qualified in its entirety by reference to, the text of the Stipulation and its accompanying Exhibits, which have been filed with the Court and are available at a link on Ophthotech's website at the Investor Relations page at https://investors.ivericbio.com/derivative-settlement.

In connection with the Settlement of the Derivative Actions, Ophthotech's Board shall adopt and maintain the corporate governance measures (the "Corporate Governance Measures") described below within sixty (60) days after the Court's final approval of the proposed Settlement. The Corporate Governance Measures shall remain in effect for a period of no less than four (4) years following final settlement approval, except for modifications required by applicable law, regulation, or fiduciary duty, or upon a Change in Control Event, in which case all duties and obligations to maintain the Corporate Governance Measures shall become subject to the good faith exercise of the succeeding board's or controlling group's or entity's business judgment. The Corporate Governance Measures may be amended or eliminated if a majority of the independent members of the Board determine in a good faith exercise of their business judgment that the implementation or maintenance of the Corporate Governance Measure(s) would be contrary to applicable laws or regulations, including the Board's fiduciary duties. In such event, the independent directors, to the extent their fiduciary obligations allow based upon their good faith exercise of business judgment, shall adopt an amended or substitute reform that addresses the same goals, purposes and/or functions of the original Corporate Governance Measure(s) as soon as practicable. Any changes made pursuant to this provision shall be published in the Company's next regular quarterly filing with the SEC.

CORPORATE GOVERNANCE MEASURES

1. **CORPORATE GOVERNANCE MEASURES TO BE IMPLEMENTED AND MAINTAINED BY IVERIC BIO, INC. (f/k/a/ OPHTHOTECH CORPORATION) AS A RESULT OF THE SETTLEMENT**

- In addition to the prior Board changes already implemented in the context of the Derivative Actions (as referenced in Section 2), the Board shall appoint another new independent

board member. The Board shall retain a third-party search firm to identify a pool of candidates to fill the new board position.[2]

- The Board shall ensure that at all times at least fifty-five percent (55%) of its members satisfy the requirements of Nasdaq Rule 5605(a)(2) for determining the "independence" of independent directors.

- The Board shall identify and designate a lead independent director in the event that the positions of CEO and Chairman are in the future held by the same individual. The responsibilities of the lead independent director, if one is designated, shall include (among other things): (i) working directly with management and the Board to ensure the preparation of meeting agendas, materials and schedules; (ii) assessing and advising the Board as to the quality, quantity, and timeliness of the information provided to the Board by management to assist the Board in performing its oversight duties; (iii) approving the agenda for, and moderating executive sessions of, the Board, and acting as principal liaison between the Board and management on sensitive issues; (iv) acting as liaison between the independent directors and the Chairman of the Board and management (however, each director is free to communicate directly with the Chairman of the Board and management); and (v) leading the Board's and the Compensation Committee's evaluation of the performance of the Company's CEO.

- In conducting a formal broad search for board of director candidates, the Board shall instruct any search firm engaged for such purpose that the initial pool of candidates shall be comprised of at least 50% of women and racially or ethnically diverse candidates, with at least 25% of those candidates being racially or ethnically diverse.

- The Board shall limit directors from serving as board members at "direct competitors" of the Company at any time.

    - "Direct competitors" shall be defined as "any company that engages in the research, development or commercialization of pharmaceutical or diagnostic products to treat (i) each of Stargardt disease, Best disease, leber congenital amaurosis (subtype 10), Usher syndrome type 2A-related inherited retinal diseases and rhodopsin-mediated autosomal dominant retinitis pigmentosa via any mechanism of action, (ii) ocular diseases whose primary mechanism of action is directed at the C5 molecule and/or its receptor or (iii) GA or AMD whose primary mechanism of action is directed at the HtrA1 enzyme."

[2] On January 5, 2022, the Board of Directors of the Company elected Christine Ann Miller as a Director of the Company. The election of Ms. Miller was intended to satisfy this Measure, and the Settling Parties agree the timing of the appointment (prior to final approval of the Settlement Agreement) shall not be used as a basis for any party to assert that the appointment of Ms. Miller does not satisfy this Measure.

- Absent extenuating circumstances, directors shall be required to attend either in person or virtually the annual shareholder meeting.

- The Company shall adopt a formal Charter for the management-level Disclosure Committee, which is attached hereto as Exhibit A-1 to the Stipulation, reflecting the duties and responsibilities of the Disclosure Committee. The Charter shall provide, among other duties and responsibilities of the Disclosure Committee, that the Disclosure Committee is responsible for:

    - Reviewing in advance the Company's quarterly earnings press releases and related materials (such as earnings conference call scripts) with respect to the adequacy and accuracy of the disclosures included therein;

    - Reviewing transcripts of analyst conference calls and other investor presentations with respect to the accuracy of any disclosures made, advising the Audit Committee of any corrections that the Disclosure Committee determines need to be made, and oversight with respect to the drafting of any required corrective disclosures;

    - Preparing and submitting to the Board a written report whenever any new material disclosure risks are identified concerning developments in the Company's clinical trials and drug approval efforts;

    - Providing a written report to the Audit Committee, at least quarterly, regarding potential or actual material disclosure issues identified; and

    - Providing a report to the Board, at least annually, summarizing its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Research and Development Committee (which was created in the context of the Derivative Actions) shall be amended to provide (among other things) that the Research and Development Committee shall be responsible for: (i) reviewing and evaluating the design of the Company's clinical trials; (ii) tracking and evaluating the progress of all ongoing clinical trials; (iii) tracking the Company's ongoing relationships with any regulatory agency governing the clinical trials, including without limitation, the FDA; and (iv) working in conjunction with the Company's management-level Disclosure Committee and the Audit Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the status of any clinical trials undertaken by the Company, as well as communications with any regulatory agency governing the clinical trials, including without limitation, the FDA. The Research and Development Committee shall ensure that the Audit Committee and the Board are promptly made aware when any issues arising out of a clinical trial are considered material by the Research and Development Committee. The Research and Development Committee shall report at least annually to the Board with respect to its activities, conclusions, and recommendations for the past year and its agenda for the coming year.

- The Charter of the Audit Committee shall be amended to include the following additional responsibilities:

    - The Audit Committee shall receive quarterly (and more often as warranted) updates from the Chief Financial Officer and/or the Company's management-level Disclosure Committee regarding the efforts of the Disclosure Committee. The Audit Committee shall work in conjunction with the Disclosure Committee and the Research and Development Committee to facilitate the Board's oversight of disclosure controls with respect to the Company's public disclosures regarding the status of any clinical trials undertaken by the Company, as well as interactions with the FDA.

    - The Audit Committee shall receive quarterly (and more often as necessary) updates from the Company's management on its risk management process. The Audit Committee shall report to the Board whenever any material risks relating to the Company's legal and/or regulatory compliance are identified, including with respect to recommendations regarding proposals for mitigating these risks, as well as relevant considerations relating to the Company's public disclosures of these risks.

    - The Audit Committee shall receive reports from and coordinate with the Research and Development Committee regarding the integrity and accuracy of the Company's press releases and regulatory filings with respect to its clinical trials and studies. In the event the Research and Development Committee presents the Audit Committee with information concerning any developments related to a clinical trial that are sufficiently material to trigger a disclosure obligation, the Audit Committee shall assess whether any corrective or other disclosures are required.

    - The Audit Committee shall receive annually a report listing all trades in the Company's securities engaged in by Section 16 officers of the Company.

- The Charter of the Nominating and Corporate Governance Committee shall be amended to provide that the Committee shall meet either in-person or virtually with each prospective new Board member prior to his or her nomination to the Board.

- The Charter of the Compensation and Talent Strategy Committee shall be amended to provide that: (i) in its consideration of compensation recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; (ii) in its consideration of severance arrangements recommendations with respect to the Company's executive officers, the Committee will take into account performance as it relates to both legal compliance and compliance with the Company's internal policies and procedures; and (iii) the Committee shall consist of at least three (3) members.

- As an initial action item following the Company's commercialization of one or more of its therapeutic product candidates ("commercialization"), in the event the Company does not yet have a Chief Compliance Officer, the Company will appoint a Chief Compliance Officer as soon as is practicable, unless the Audit Committee, in conjunction with input from an outside independent consultant, determines in good faith that it is not in the Company's best interests, taking into account, among other considerations, the regulatory compliance obligations and financial resources of the Company. In the event the Company has not appointed a Chief Compliance Officer within six (6) months of commercialization, the Audit Committee shall provide a report regarding its determinations, the reasons for not appointing a Chief Compliance Officer, and how the duties of a Chief Compliance Officer otherwise will be fulfilled by other existing positions to the Board.

- The Insider Trading Policy shall be amended to incorporate the following revisions, which are reflected in the amended Insider Trading Policy attached hereto as Exhibit A-2 to the Stipulation:

    - The Company shall undertake an annual review reasonably intended to ensure that the Insider Trading Policy remains up-to-date with respect to insider trading laws and regulations.

    - The Company shall obtain annual written certifications from directors, and executive officers indicating that those individuals have read and understood the terms of the Insider Trading Policy.

    - In the next quarterly filing following the approval of a new or amended Rule 10b5-1 plan for any director or executive officer, the Company shall disclose: (1) the name of the plan enrollee; (2) the date the plan was entered into; and (3) the date the plan expires, if applicable.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, during the pendency of any Company-funded open market stock buy-back program, no director or officer subject to reporting obligations under Section 16 of the Exchange Act shall be permitted to sell stock of the Company.

    - Except as provided in Section 2.2(b) of the Insider Trading Policy, officers subject to reporting obligations under Section 16 of the Exchange Act shall be prohibited from trading securities of the Company for the period of time beginning no later than the fifteenth (15th) day of the last month of each quarter and ending upon the completion of the second full trading day after the public announcement of earnings each quarter.

    - Any failure to comply with the Insider Trading Policy by any employee of the Company will result in an assessment by the Company concerning appropriate disciplinary action, which may include reimbursement for any fines, fees, or expenses incurred by the Company as a result of any noncompliance with the Insider Trading Policy, cancellation of outstanding stock options, disqualification

from performance-based compensation, and employee discipline up to and including termination.

- The Clawback Policy shall be amended to provide the following, which is reflected in the amended Clawback Policy attached hereto as Exhibit A-3 to the Stipulation:

    - Upon any restatement of the Company's financial results, the Board shall oversee an investigation reasonably intended to assess (1) whether any compensation, including in particular any incentive-based compensation (including stock options awarded as compensation), was paid to the Company's CEO, CFO, or any other executive officer on the basis of any misstated financial results; and (2) whether the restatement was caused by fraud or intentional misconduct (as defined in Exhibit A-3 to the Stipulation) of the CEO, CFO, or any other executive officer.

    - The Company shall disclose in its Compensation Discussion and Analysis a summary of the Board's investigation.

- The Board shall maintain and publish on the Company's website the following policies (as revised, where appropriate) for the entirety of the Compliance Term:

    - Insider Trading Policy

    - Related Person Transactions Policy

    - Clawback Policy

- The Code of Business Conduct and Ethics shall be amended to require that the Company institute mandatory annual employee training concerning applicable policies and codes of conduct, as appropriate given the employee's role within the Company.

- The Board shall maintain the provision in the Corporate Governance Guidelines that requires new directors to participate in the Company's orientation program for new directors.

- The Board shall amend the Corporate Governance Guidelines to require director participation in continuing education for directors, as the Board determines appropriate.

- The Board shall publish the revised Corporate Governance Guidelines and Code of Business Conduct and Ethics on the Company's website and include a link to those documents in the Company's proxy statements.

- The Board shall publish all Board committee charters, as revised, on the Company's website for the at least the duration of the Compliance Term.

- In the event that a final non-appealable judgment is entered against defendant Guyer and/or defendant Patel following summary adjudication or trial, including the conclusion of any and all appeals, in *Micholle v. Ophthotech Corporation, et al.*, Case No. 1:17-cv-00210-

VSB-GWG (S.D.N.Y.) (the "Securities Class Action") for violation(s) of federal securities laws in which defendant Guyer and/or defendant Patel is found to have acted willfully in bad faith, Ophthotech shall, to the extent not inconsistent with applicable legal obligations, including but not limited to the Company's legal obligations to defendants Guyer and Patel contained in the Company's Fourth Amended and Restated Certificate of Incorporation, Paragraph TENTH, pursue sums previously paid pursuant to the Company's advancement and/or indemnification obligations to or for the benefit of the defendant(s) against whom such a final non-appealable judgment is entered.

2. CORPORATE GOVERNANCE ENHANCEMENTS AND OTHER CHANGES ALREADY IMPLEMENTED

- The Derivative Actions were a factor considered by the Company and its Board in connection with modifications it made to its board composition and structure in the period between (1) the filing of such litigation and the transmittal of litigation demands and (2) the parties' agreement in principle in connection with mediation to settle these Derivative Actions. Such modifications include the appointment of new, non-defendant directors to fill vacancies created by director departures.

- Concerns, including as expressed by the derivative plaintiffs in litigation and the demanding shareholders in correspondence and demands, were substantial contributing factors to the following corporate governance measures and enhancements:

    - Adoption of the Clawback Policy

    - Adoption of the Stock Retention and Ownership Guidelines

    - Amendments to the Code of Business Conduct and Ethics

VII. PLAINTIFFS' COUNSEL'S SEPARATELY NEGOTIATED AGREED-TO ATTORNEYS' FEES AND EXPENSES

After negotiating the principal terms of the Settlement, counsel for the Settling Parties, the SLC, and the Individual Defendants' insurers, acting by and through their respective counsel, with the substantial assistance of the Mediator, separately negotiated the attorneys' fees and expenses the Individual Defendants would cause their insurers to pay to Plaintiffs' Counsel based on the substantial benefits conferred upon Ophthotech by the Settlement.

In consideration of the substantial benefits conferred upon Ophthotech as a direct result of the Settlement and the efforts of Plaintiffs and Plaintiffs' Counsel in the Derivative Actions, and subject to Court approval, the Individual Defendants shall cause their insurers to pay Plaintiffs'

Counsel attorneys' fees and expenses in the total amount of $2,450,000 (the "Fee and Expense Amount"). The members of the SLC, in the good faith exercise of their business judgment, have approved the agreed-to Fee and Expense Amount in light of the substantial benefits conferred upon Ophthotech as a result of the Settlement and Plaintiffs' Counsel's efforts in this litigation.

The Settling Parties further stipulated that Plaintiffs' Counsel may apply to the Court for service awards of up to $5,000 for each of the Plaintiffs, only to be paid upon Court approval, and to be paid from the Fee and Expense Amount, in recognition of Plaintiffs' participation and effort in the prosecution of the Derivative Actions.

VIII. SETTLEMENT HEARING

On January 20, 2023, at 4:00 p.m., the Court will hold the Settlement Hearing at the United States District Court for the Southern District of New York, 40 Foley Square, New York, New York 10007. At the Settlement Hearing, the Court will consider whether the terms of the Settlement are fair, reasonable, and adequate and thus should be finally approved, whether the separately negotiated Fee and Expense Amount and Plaintiffs' service awards should be approved, and whether the Derivative Actions should be dismissed with prejudice pursuant to the Stipulation.

Pending the Court's determination as to final approval of the Settlement, Plaintiffs and all Current Company Stockholders are barred and enjoined from commencing, instituting, filing, intervening in, participating in, receiving any benefit from, or prosecuting any action, including without limitation any derivative action, asserting any of the Released Claims against any of the Released Persons.

IX. RIGHT TO ATTEND SETTLEMENT HEARING

Any current Ophthotech stockholder may, but is not required to, appear in person at the Settlement Hearing. If you want to be heard at the Settlement Hearing, then you must first comply

with the procedures for objecting, which are set forth below. The Court has the right to change the hearing date or time without further notice or to hold it telephonically or via another remote process. Thus, if you are planning to attend the Settlement Hearing, you should confirm the date and time before going to the Court. Current Company Stockholders who have no objection to the Settlement do not need to appear at the Settlement Hearing or take any other action.

X. RIGHT TO OBJECT TO THE PROPOSED DERIVATIVE SETTLEMENT AND PROCEDURES FOR DOING SO

Any current Ophthotech stockholder may appear and show cause, if he, she, or it has any reason why the Settlement of the Derivative Actions should not be approved as fair, reasonable, and adequate, or why a judgment should not be entered thereon, or why the separately negotiated attorneys' fees and expenses should not be approved. You must object in writing, and you may request to be heard at the Settlement Hearing. If you choose to object, then you must follow these procedures.

A. You Must Make Detailed Objections in Writing

Any objections must be presented in writing and must contain the following information:

1. Your name, legal address, and telephone number;

2. The case name and number (*Pacheco v. Guyer*, Case No. 1:18-cv-07999);

3. Proof of being an Ophthotech stockholder as of the Record Date, January 27, 2022.

4. The date(s) you acquired your Ophthotech shares;

5. A statement of each objection being made;

6. Notice of whether you intend to appear at the Settlement Hearing (you are not required to appear); and

7. Copies of any papers you intend to submit to the Court, along with the names of any witness(es) you intend to call to testify at the Settlement Hearing and the subject(s) of their testimony.

The Court may not consider any objection that does not substantially comply with these requirements.

B. You Must Timely Deliver Written Objections to the Court

All written objections and supporting papers must be submitted to the Court either by mailing them to:

Clerk of the Court
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
40 Foley Square
New York, New York 10007

OR by filing them in person at any location of the United States District Court for the Southern District of New York.

YOUR WRITTEN OBJECTIONS MUST BE POSTMARKED OR ON FILE WITH THE CLERK OF THE COURT NO LATER THAN DECEMBER 30, 2022.

Unless the Court orders otherwise, your objection will not be considered unless it is timely filed with the Court.

Your written objection must also be mailed to:

Plaintiffs' Counsel:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5060 Shoreham Place, Suite 300
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

Defendants' Counsel:

Michael G. Bongiorno
Jeremy T. Adler
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Counsel for Defendants and Nominal Defendant

Jordan D. Hershman
MORGAN, LEWIS & BOCKIUS LLP
One Federal Street
Boston, MA 02110

Counsel for Defendants David R. Guyer and Samir C. Patel

Any Person or entity who fails to object or otherwise request to be heard in the manner prescribed above will be deemed to have waived the right to object to any aspect of the Settlement as incorporated in the Stipulation or otherwise to be heard (including the right to appeal) and will be forever barred from raising such objection or request to be heard in this or any other action or proceeding, and, unless otherwise ordered by the Court, shall be bound by the Judgment to be entered and the releases to be given.

XI. RELEASES

Upon the Effective Date, the Releasing Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged with prejudice and on the merits, to the fullest extent permitted by law, each and all of the Released Persons from and with respect to each and all of the Released Claims (including Unknown Claims), and will be forever barred and enjoined from commencing, instituting, or prosecuting any action or proceeding, in any forum, asserting any of the Released Claims against any of the Released Persons, including but not limited to any and all

claims arising out of, relating to, or in connection with the defense, settlement, or resolution of the Derivative Actions against the Released Persons.

Upon the Effective Date, each of the Defendants shall be deemed to have fully, finally, and forever released, relinquished, and discharged Plaintiffs and Plaintiffs' Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection with the institution, prosecution, assertion, settlement, or resolution of the Derivative Actions or the Released Claims.

Upon the Effective Date, each of the Settling Parties shall be deemed to have fully, finally, and forever released, relinquished, and discharged the members of the SLC and SLC Counsel from all claims (including Unknown Claims), arising out of, relating to, or in connection with the investigation, settlement, or resolution of the Derivative Actions or the Released Claims.

"Released Claims" means any and all manner of claims, demands, rights, liabilities, losses, obligations, duties, damages, costs, debts, expenses, interest, penalties, sanctions, fees, attorneys' fees, actions, potential actions, causes of action, suits, agreements, judgments, decrees, matters, issues and controversies of any kind, nature or description whatsoever, whether known or unknown, disclosed or undisclosed, accrued or unaccrued, apparent or not apparent, foreseen or unforeseen, matured or not matured, suspected or unsuspected, liquidated or not liquidated, fixed or contingent, including without limitation Unknown Claims (as defined in paragraph 1.33 of the Stipulation), whether based on state, local, foreign, federal, statutory, regulatory, common or other law or rule, brought or that could be brought by Ophthotech or derivatively on behalf of Ophthotech that arise out of or relate to: (i) the allegations asserted in the Derivative Actions; or (ii) the Settlement, except for any claims to enforce the Settlement. Excluded from the term "Released Claims" are all claims asserted in the Securities Action.

"Released Persons" means collectively, Ophthotech, the Individual Defendants, and their Related Persons. "Related Persons" means: (i) with regard to each Individual Defendant, the Individual Defendants' spouses, marital communities, immediate family members, heirs, executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns or any other entity in which any Individual Defendant has a controlling interest, and each and all of their respective past and present officers, directors, employees, agents, affiliates, parents, subsidiaries, divisions, attorneys, accountants, auditors, advisors, insurers, co-insurers, re-insurers, heirs, executors, personal representatives, estates, administrators, trusts, predecessors, successors, and assigns; and (ii) with regard to Ophthotech, all past or present agents, officers, directors, attorneys, accountants, auditors, advisors, insurers, co-insurers, reinsurers, partners, controlling shareholders, joint venturers, related or affiliated entities, advisors, employees, affiliates, predecessors, successors, parents, subsidiaries, insurers, and assigns for Ophthotech.

"Releasing Parties" means Plaintiffs, all other Current Company Stockholders, Plaintiffs' Counsel, and Ophthotech

XII. HOW TO OBTAIN ADDITIONAL INFORMATION

This Notice summarizes the Stipulation. It is not a complete statement of the events of the Derivative Actions or the Settlement contained in the Stipulation.

You may inspect the Stipulation and other papers in the Derivative Actions at the United States District Court Clerk's office at any time during regular business hours of each business day. The Clerk's office is located at the United States District Court for the Southern District of New York, 40 Foley Square, New York, New York 10007. However, you may visit the Company's website to inspect the Stipulation or contact counsel listed below. The Clerk's office will not mail

copies to you. You may also view and download the Stipulation at https://investors.ivericbio.com/derivative-settlement.

If you have any questions about matters in this Notice, you may contact:

Brian J. Robbins
Craig W. Smith
Shane P. Sanders
Robbins LLP
5060 Shoreham Place, Suite 300
San Diego, CA 92122

Counsel for Plaintiff Luis Pacheco

PLEASE DO NOT CALL, WRITE, OR OTHERWISE DIRECT QUESTIONS TO EITHER THE COURT OR THE CLERK'S OFFICE.

DATED: November 3, 2022

BY ORDER OF THE COURT
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK