# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2014

OR

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

Commission file number: 001-36080

### **Ophthotech Corporation**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

20-8185347

(I.R.S. Employer Identification Number)

One Penn Plaza, 19<sup>th</sup> Floor New York, NY (Address of principal executive offices)

10119

(Zip Code)

(212) 845-8200

(Registrant's telephone number, including area code)

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No o

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer  $\boldsymbol{x}$ 

Smaller reporting company o

(Do not check if a smaller reporting company)

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

As of July 31, 2014 there were 33,486,578 shares of Common Stock, \$0.001 par value per share, outstanding.

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#### 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 product development plans, 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 timing, costs, conduct and outcome of our Phase 3 clinical trials of Fovista administered in combination with anti-VEGF drugs for the treatment of wet age-related macular degeneration, or AMD, including statements regarding the timing and the availability of, and the costs to obtain, initial top-line results from, and the completion of such trials and the timing of regulatory filings;
- our plans to further evaluate the potential benefit of Fovista in wet AMD in other clinical trials, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet medical need, including statements regarding the timing of the initiation of, and the costs to obtain and timing of receipt of initial results from, and the completion of related clinical trials;
- our plans to develop Zimura, including our plans to initiate a Phase 2/3 clinical trial evaluating the safety and efficacy of Zimura for the treatment of patients with geographic atrophy, a severe form of dry AMD, and a Phase 2 clinical trial evaluating the safety and efficacy of Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of certain forms of wet AMD, including statements regarding the timing of the initiation of, and the costs to obtain and timing of receipt of initial results from, and the completion of related clinical trials;
- the timing of and our ability to obtain marketing approval of Fovista, Zimura and other product candidates we may develop, and the ability of Fovista, Zimura and other product candidates we may develop to meet existing or future regulatory standards;
- · our ability to maintain a successful collaborative relationship with Novartis Pharma AG, including the ability to achieve potential milestone payments;
- the potential advantages of Fovista and Zimura;
- the rate and degree of potential market acceptance and clinical utility of Fovista and Zimura;
- · our estimates regarding the potential market opportunity for Fovista and Zimura;
- · the potential receipt of revenues from future sales of Fovista and Zimura;
- · our sales, marketing and distribution capabilities and strategy;
- · our ability to establish and maintain arrangements for manufacture of Fovista, Zimura and other product candidates we may develop;
- $\cdot \quad \text{our ability to in-license or acquire complementary products, product candidates or technologies;}\\$
- · our intellectual property position;
- · our expectations related to our use of available cash;
- · our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- · the impact of 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 you 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 "Risk Factors" section, 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, 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 completely and with the understanding that our actual future results may be materially different from what we expect. 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.

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#### PART I—FINANCIAL INFORMATION

#### Item 1. Financial Statements.

#### **OPHTHOTECH CORPORATION**

Unaudited Balance Sheets (in thousands, except share and per share data)

	Jı	une 30, 2014	Dec	ember 31, 2013
Assets				
Current assets				
Cash and cash equivalents	\$	248,498	\$	210,596
Available for sale securities		188,733		_
Prepaid expenses and other current assets		4,087		6,804
Deferred tax assets		837		<u> </u>
Total current assets		442,155		217,400
Available for sale securities		15,255		_
Property and equipment, net		826		27
Deferred tax assets, non-current		19,635		
Security deposits		255		255
Total assets	\$	478,126	\$	217,682
Liabilities and Stockholders' Equity				
Current liabilities				
Accrued clinical drug supplies and trial costs	\$	1,783	\$	2,485
Accounts payable and accrued expenses		4,039		3,810
Income tax payable		29,540		_
Total current liabilities		35,362		6,295
Deferred revenue, long-term		200,000		_
Royalty purchase liability		83,333		41,667
Total liabilities		318,695		47,962
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, 33,452,008 and 31,413,208 shares issued				
and outstanding at June 30, 2014 and December 31, 2013, respectively		33		31
Additional paid-in capital		415,604		352,739
Accumulated deficit		(256,231)		(183,050)
Accumulated other comprehensive income		25		_
Total stockholders' equity		159,431		169,720
Total liabilites and stockholders' equity	\$	478,126	\$	217,682

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

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## **OPHTHOTECH CORPORATION Unaudited Statements of Operations**

(in thousands, except per share data)

	 Three Months l	Ended	June 30,	Six Months Ended June 30,			une 30,
	2014		2013	2014			2013
Costs and expenses:							
Research and development	\$ 34,707	\$	4,345	\$	49,084	\$	6,734
General and administrative	7,570		3,242		13,919		4,980
Total costs and expenses	 42,277		7,587		63,003		11,714
Loss from operations	 (42,277)		(7,587)		(63,003)		(11,714)
Interest income (expense)	72		(1,097)		116		(1,454)
Loss on extinguishment of debt	_		(1,196)		_		(1,196)
Other loss	_		(126)		<u> </u>		(260)
Net loss before income tax provision	 (42,205)		(10,006)		(62,887)		(14,624)
Income tax provision	(10,294)		_		(10,294)		_

Net loss		(52,499)	(10,006)	(73,181)	 (14,624)
Add: accretion of preferred stock dividends		_	(1,858)	_	(3,600)
Net loss attributable to common stockholders	\$	(52,499)	\$ (11,864)	\$ (73,181)	\$ (18,224)
Net loss attributable to common stockholders per share :					
Basic and diluted	\$	(1.57)	\$ (8.07)	\$ (2.23)	\$ (12.40)
Weighted average common shares outstanding:				 	
Basic and diluted		33,373	1,470	32,830	1,470
	_				

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

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#### **OPHTHOTECH CORPORATION Unaudited Statements Comprehensive Loss** (in thousands)

	Three Months Ended June,					Six Months Ended June 30,			
		2014 2013		2014			2013		
Net loss	\$	(52,499)	\$	(10,006)	\$	(73,181)	\$	(14,624)	
Other comprehensive income:	Ψ	(32,433)	Ψ	(10,000)	Ψ	(75,101)	Ψ	(14,024)	
Unrealized gain on available for sale securities, net of taxes		7		_		25		_	
Other comprehensive income		7		_		25		_	
Comprehensive loss	\$	(52,492)	\$	(10,006)	\$	(73,156)	\$	(14,624)	

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

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Proceeds from royalty purchase agreement

Net cash provided by financing activities

# **OPHTHOTECH CORPORATION**

Unaudited Statements of Cash Flows (in thousands)		
	Six months en	ided Tune 30
	2014	2013
Operating Activities		
Net loss	\$ (73,181)	\$ (14,624)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	43	10
Amortization of debt issuance costs	_	88
Accretion of debt discount	_	87
Amortization of premium and discounts on investment securities	802	_
Non-cash change in fair value of warrant liability	_	260
Loss on extinguishment of debt	_	1,196
Deferred tax provision	(19,246)	_
Share-based compensation	5,912	460
Excess tax benefits from share-based compensation	(1,244)	_
Changes in operating assets and liabilities:		
Prepaid expense and other current assets	2,717	(62)
Accrued interest receivable	78	_
Accrued clinical drug supplies and trial costs	(702)	1,088
Accounts payable and accrued expenses	229	1,062
Income tax payable	29,540	_
Deferred revenue	200,000	_
Net cash provided by (used in) operating activities	144,948	(10,435)
Investing Activities		
Purchase of marketable securities	(244,824)	_
Maturities of marketable securities	40,000	_
Purchase of property and equipment	(842)	_
Net cash used in investing activities	(205,666)	_
Financing Activities		
Payment of debt issuance costs	_	(43)
Proceeds from issuance of common stock	300	_
Proceeds from follow-on public offering, net	55,409	_
Excess tax benefits from share-based compensation	1,244	_
Repayment of venture debt facility, net	· _	(12,005)
Proceeds from issuance of preferred stock, net	_	16,365

41,667

98,620

41,667

45,984

	_		 _
Net change in cash and cash equivalents		37,902	35,549
Cash and cash equivalents			
Beginning of period		210,596	4,305
End of period	\$	248,498	\$ 39,854
Supplemental disclosure of cash paid			
Interest	\$	_	\$ 1,524
Income Taxes	\$	_	\$ _
Supplemental disclosures of cash flow information			
Accreted dividends on Series A, Series A-1, Series of B, B-1 and Series C Preferred Stock	\$	_	\$ 3,600

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

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#### OPHTHOTECH CORPORATION

Notes to Unaudited Financial Statements (tabular dollars and shares in thousands, except per share data)

#### 1. Business

#### **Description of Business and Organization**

Ophthotech Corporation (the "Company" or "Ophthotech") was incorporated on January 5, 2007, in Delaware. The Company is a biopharmaceutical company specializing in the development of novel therapeutics to treat diseases of the back of the eye, with a focus on developing therapeutics for age-related macular degeneration, or AMD. The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to product candidates, business planning, raising capital and developing its product candidates. The Company operates in one business segment.

#### Liquidity

Since the Company's inception, it has experienced significant cash outflows in funding its operations. The Company reported a net loss of \$73.2 million for the six months ended June 30, 2014 and \$14.6 million for the six months ended June 30, 2013. As of June 30, 2014, the Company had an accumulated deficit of \$256.2 million. To date, the Company has not generated any revenue from product sales and has financed its operations primarily through private placements of its preferred stock, venture debt borrowings, its royalty purchase and sale agreement with Novo A/S (the "Novo Agreement"), its initial public offering ("IPO"), which closed on September 30, 2013, a follow-on public offering, which closed on February 18, 2014, and its license and commercialization agreement with Novartis Pharma AG (the "Novartis Agreement"), which it entered into on May 19, 2014. The Company issued and sold an aggregate of 8,740,000 shares of common stock in its IPO at a public offering price of \$22.00 per share. The Company received net proceeds from the IPO of \$175.6 million, after deducting underwriting discounts and commissions and other offering expenses. On February 18, 2014, the Company closed a follow-on public offering of 2,628,571 shares of common stock at a public offering price of \$31.50 per share of common stock. The Company sold 1,900,000 shares and 728,571 shares were sold by selling stockholders. Net proceeds to the Company were approximately \$55.4 million, after deducting underwriting discounts and commissions and other offering expenses. In May 2014, the Company received an upfront payment of \$200.0 million in connection with a licensing and commercialization agreement with Novartis for the rights to commercialize Fovista, a product candidate currently in Phase 3 clinical trials, outside the United States. In connection with the receipt of the payment from Novartis, the Company made a milestone payment in June 2014 of approximately \$19.8 million under one of its agreements. The Company currently estimates that it will make income tax payments of approximately \$29.5 million during the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement. The Company has devoted substantially all of its financial resources and efforts to research and development and expects to continue to incur significant expenses and losses over the next several years. The Company's net losses may fluctuate significantly from quarter to quarter and year to vear.

To fully execute its business plan, the Company will need to complete certain research and development activities and clinical trials. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities will span many years and require substantial expenditures to complete and may ultimately be unsuccessful. The Company expects to obtain initial, top-line data from its Phase 3 clinical program for Fovista in 2016. As of June 30, 2014, the Company had cash, cash equivalents, and marketable securities of \$452.5 million. The Company also had \$318.7 million in total liabilities as of June 30, 2014, including long-term liabilities of \$283.3 million relating to the Novo Agreement and deferred revenue associated with the Novartis Agreement. The Company believes its cash, cash equivalents and marketable securities will be sufficient to fund its operations and capital expenditure requirements, as currently planned, through the end of 2017.

The current Phase 3 clinical program for Fovista is expected to continue through at least 2017, and substantial expenditures to complete the Phase 3 clinical program will be required after the expected receipt of initial, top-line data and to fund the Company's other development programs. The Company expects to continue to experience significant cash outflows until such time, if ever, as it can generate substantial product revenues. These cash outflows may be in excess of the Company's existing capital resources and the Company may need to finance its cash needs through a combination of equity and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. There can be no assurance that such funds will be available, or if available, on terms favorable to the Company. The Company faces the normal risks associated with a pre-commercial company, including but not limited to the risk that the Company's research and development activities will not be successfully completed, that adequate patent protection for the Company's technology will not be obtained, that any products developed will not obtain necessary government regulatory approval and that any approved products will not be commercially viable. In addition, the Company operates in an environment of rapid change in technology, substantial competition from pharmaceutical and biotechnology companies and is dependent upon the services of its employees and its consultants. The Company's capital requirements will depend on many factors, including the success of its development and commercialization of its product candidates and whether it pursues the acquisition or in-licensing and subsequent development of additional product candidates. Even if the Company succeeds in developing and

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commercializing one or more of its product candidates, it may never achieve sufficient sales revenue to achieve or maintain profitability.

#### 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The accompanying unaudited financial information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 has been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to such rules and regulations. The December 31, 2013 balance sheet was derived from the Company's audited financial statements. These interim financial statements should be read in conjunction with the notes to the financial statements contained in the Company's Annual Report on Form 10-K ("Annual Report") for 2013, as filed with the Securities and Exchange Commission on March 11, 2014.

In the opinion of management, the unaudited financial information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013, reflects all adjustments, which are normal recurring adjustments, necessary to present a fair statement of financial position, results or operations and cash flows. The results of operations for the three and six months ended June 30, 2014 and 2013 are not necessarily indicative of the operating results for the full fiscal year or any future period.

#### **Use of Estimates**

The preparation of financial statements and related disclosures in conformity with 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 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 share-based compensation, accounting for research and development costs 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 three months or less when purchased to be cash equivalents. The carrying amounts reported in the Balance Sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

#### **Available for Sale Securities**

The Company considers securities with original maturities of greater than three months to be available for sale securities. Securities under this classification are recorded at fair value and unrealized gains and losses within accumulated other comprehensive income. The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The Company evaluates securities with unrealized losses to determine whether such losses, if any, are other than temporary.

#### **Revenue Recognition**

To date, the Company has not generated any revenue. In the future, the Company may generate revenues from a combination of product sales and license fees, milestone payments and research and development activity-related payments and royalties in connection with the Novartis Agreement. The terms of this agreement and other potential collaboration or commercialization agreements the Company may enter into generally contain multiple elements, or deliverables, which may include (i) licenses, or options to obtain licenses, to certain of the Company's technology and products, (ii) research and development activities to be performed on behalf of the collaborative partner, and (iii) in certain cases, services in connection with the manufacturing of pre-clinical and clinical material. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

When evaluating multiple element arrangements, the Company considers whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make

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judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE is available. Determining the best estimate of selling price for a deliverable requires significant judgment. The Company uses BESP to estimate the selling price for licenses to the Company's proprietary technology, since the Company often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where the Company utilizes BESP to determine the estimated selling price of a license to the Company's proprietary technology, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's best estimate of selling price, the Company evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

When management believes the license to its intellectual property and products has stand-alone value, the Company generally recognizes revenue attributed to the license upon delivery. When management believes such a license does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributed to the license on a straight-line basis over the Company's contractual or estimated performance period, which is typically the term of the Company's research and development obligations. If management cannot reasonably estimate when the Company's performance obligation ends, then revenue is deferred until management can reasonably estimate when the performance obligation ends. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

At the inception of arrangements that include milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

The Company aggregates its milestones into three categories: (i) clinical and development milestones, (ii) regulatory milestones, and (iii) commercial milestones. Clinical and development milestones are typically achieved when a product candidate advances into a defined phase of clinical research or completes such phase. Regulatory milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other global regulatory authorities. For example, a milestone payment may be due to the Company upon the FDA's acceptance of an NDA. Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount.

Revenues from clinical and development and regulatory milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, are recognized upon successful accomplishment of the milestones. With regard to the Novartis Agreement, the Company has concluded that the clinical and development milestones and certain regulatory milestones are not substantive and that the regulatory approval milestones are substantive. Milestones payments received that are not considered substantive are included in the allocable arrangement consideration and are recognized as revenue in proportion to the relative-selling price allocation established at the inception of the arrangement. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

#### **Concentration of Credit Risk**

The Company's financial instruments that are exposed to concentration of credit risk consist primarily of cash and cash equivalents and available for sale securities. The Company maintains its cash in bank accounts, which, at times exceed federally insured limits. The Company maintains its cash equivalents in U.S. Treasury securities with maturities less than three months and in money market funds that invest primarily in U.S. Treasury securities.

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The Company's available for sale securities are also invested in U.S. Treasury securities. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk on its cash, cash equivalents and available for sale securities.

#### **Foreign Currency Translation**

The Company maintains a bank account in a foreign currency. The Company considers the U.S. dollar to be its functional currency. Expenses are translated at the exchange rate on the date the expense is incurred. The effect of exchange rate fluctuations on translating foreign currency assets and liabilities into U.S. dollars is included in the Statements of Operations. Foreign exchange transaction gains and losses are included in the results of operations and are not material in the Company's financial statements.

#### **Property and Equipment**

Property and equipment, which consists mainly of furniture and fixtures, computers and other equipment, and leasehold improvements, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally five to ten years, using the straight-line method.

#### **Research and Development**

Research and development expenses consist of costs associated with the development and clinical testing of Fovista, an anti-Platelet Derived Growth Factor ("PDGF") aptamer the Company is developing for use in combination with anti-VEGF drugs for treatment of wet age-related macular degeneration, or wet AMD, and Zimura, an inhibitor of complement factor C5 the Company is developing with a focus on treatment of patients with geographic atrophy, a severe form of dry AMD. Research and development expenses consist of:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, ("CROs")
  and other vendors, contract manufacturing organizations and consultants; and
- · employee-related expenses, including salaries, benefits, travel and share-based compensation expense.

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

All research and development costs are charged to operations as incurred in accordance with ASC Topic 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.

The Company anticipates that it will continue to incur significant research and development expenses in connection with conducting its pivotal Phase 3 clinical program for Fovista and if such trials are successful, seeking marketing approval for Fovista. The Company also anticipates that its research and development expenses will increase as a result of its plan to initiate a Phase 2/3 clinical trial to evaluate the safety and efficacy of Zimura in patients with geographic atrophy in late 2014 or early 2015. In addition, the Company also expects its research and development expenses to increase as it further evaluates the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet medical need, and pursues an additional planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation. The Company expects these expenses to increase as patient enrollment increases in these trials.

#### **Income Taxes**

The Company utilizes the liability method of accounting for deferred income taxes, as set forth in ASC 740-10, *Income Taxes-Overall*. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. The Company's U.S. federal net operating losses have occurred since its inception in 2007 and as such, tax years subject to potential tax examination could apply from that date because carrying-back net operating loss opens the relevant year to audit.

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#### **Share-Based Compensation**

The Company follows the provisions of the ASC 718, *Compensation—Stock Compensation* which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and non-employee directors, including employee stock options. 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.

The Company estimates the fair value of stock options granted to employees on the date of grant using the Black-Scholes option-pricing model. Due to the lack of trading history, the Company's computation of stock-price volatility is based on the volatility rates of comparable publicly held companies over a period equal to the expected term of the options granted by the Company. The Company's computation of expected term is determined using the "simplified" method which is the midpoint between the vesting date and the end of the contractual term. The Company believes that it does not have sufficient reliable exercise data in order to justify the use of a method other than the "simplified" method of estimating the expected exercise term of employee stock option grants. The Company has paid no dividends to stockholders. 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.

For stock options granted as consideration for services rendered by non-employees, the Company recognizes expense in accordance with the requirements of ASC 505-50, *Equity Based Payments to Non-Employees*. Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the vesting period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of options granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the stock options are fully vested.

Share-based compensation expense includes stock options and restricted stock units granted to employees and non-employees and has been reported in the Company's Statements of Operations as follows:

	Three months ended June 30,			Six months ended June 30,				
		2014		2013		2014		2013
Research and development	\$	1,945	\$	262	\$	3,607	\$	330
General and administrative		1,238		90		2,305		130
Total	\$	3,183	\$	352	\$	5,912	\$	460

#### **JOBS Act**

As an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, the Company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to delay the adoption of such new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to the financial statements of other public companies. Commencing January 1, 2015, the Company will no longer qualify for such status and will need to comply with all new or revised accounting standards applicable to other public companies. The Company does not expect this prospective change in status to have a material impact on the Company's 2015 financial position or results of operations.

#### **Recent Accounting Pronouncements**

In May 2014, the FASB issued Accounting Stands Update No. 2014-09," *Revenue from Contracts with Customers (Topic 606)*," ("ASU 2014-09"). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. ASU 2014-09 is effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements and footnote disclosures.

In June 2014, the FASB issued Accounting Stands Update No. 2014-10, "Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, including an Amendment to Variable Interest Entities Guidance in Topic 810 Consolidation" ("ASU 2014-10"). The objective of the

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reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. The Company evaluated and elected early adoption of ASU 2014-10 for this filing.

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, *Comprehensive Income: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ("ASU 2013-02"). ASU 2013-02 requires an entity to present the effect of certain significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The amendments in ASU 2013-02 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU 2013-02 is effective for public companies on a prospective basis for fiscal years beginning after December 15, 2012 and for new public companies and for non-public companies for reporting periods beginning after December 15, 2013. The Company adopted this pronouncement on January 1, 2014. The Company has not reclassified any components of comprehensive income into net income for the periods presented. ASU 2013-02 requires only additional presentation and as such, there was no impact to the Company's results of operations or financial position upon adoption.

#### 3. Capitalization

On September 9, 2013, the Company effected a one-for-5.9 reverse stock split of its common stock. All share and per share data (except par value) related to common stock, options and warrants included in these financial statements and accompanying notes have been adjusted to reflect the reverse stock split for all periods presented.

On September 30, 2013, the Company closed its initial public offering of 8,740,000 shares of common stock at a price of \$22.00 per share. The net proceeds to the Company were \$175.6 million, after deducting underwriters' discounts and commissions and other offering expenses. In connection with the closing of the IPO, all of the Company's shares of redeemable convertible preferred stock outstanding at the time of the offering were automatically converted into 21,038,477 shares of common stock.

On February 18, 2014, the Company closed a follow-on public offering of 2,628,571 shares of common stock at a public offering price of \$31.50 per share of common stock. The Company sold 1,900,000 shares and 728,571 shares were sold by selling stockholders, 342,857 of which were sold by the selling stockholders upon the full exercise by the underwriters of their option to purchase additional shares in the follow-on public offering. Net proceeds to the Company were approximately \$55.4 million, after deducting underwriters' discounts and commissions and other offering expenses. The Company did not receive any proceeds from the sale of shares by the selling stockholders in the follow-on public offering.

#### 4. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. For the periods where there is a net loss attributable to common shareholders, the outstanding shares of preferred stock, stock options, and warrants have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted loss per share would be the same. The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three months ended June 30,			Six months end			ıded June 30,	
	2014		2013		2014		2013	
Basic and diluted net loss per common share calculation:								
Net loss	\$ (52,499)	\$	(10,006)	\$	(73,181)	\$	(14,624)	
Accretion of preferred stock dividends	_		(1,858)		_		(3,600)	
Net loss attributable to common share	\$ (52,499)	\$	(11,864)	\$	(73,181)	\$	(18,224)	
Weighted average common shares outstanding	33,373		1,470		32,830		1,470	
Net loss per share of common stock - basic and diluted	\$ (1.57)	\$	(8.07)	\$	(2.23)	\$	(12.40)	

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

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	Three months	ended June 30,	Six months e	nded June 30,
	2014	2013	2014	2013
Redeemable convertible preferred stock	_	18,094	_	18,094
Stock options	3,851	2,151	3,851	2,151
Warrants	27	101	27	101
Restricted stock units	25	_	25	_
Total	3,903	20,346	3,903	20,346

#### 5. Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of \$4.5 million and \$6.8 million at June 30, 2014 and December 31, 2013, respectively. Cash and cash

equivalents at June 30, 2014 and December 31, 2013 also included investments of \$244.0 million and \$203.8 million, respectively, in U.S. Treasury securities with original maturities of less than three months and in money market funds that invest in U.S. Treasury Securities.

At June 30, 2014, the Company held available for sale securities with a fair value totaling \$204.0 million. These available for sale securities consisted of U.S. Treasury securities. At June 30, 2014, \$188.7 million of the available for sale securities had maturities less than one year, and \$15.3 million had maturities of greater than one year. The Company evaluates securities with unrealized losses, if any, to determine whether such losses are other than temporary. The Company has determined that there were no other than temporary declines in fair values of its investments as of June 30, 2014. As of December 31, 2013, the Company did not hold any available for sale securities.

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

	As of June 30, 2014								
	 Cost Fair Value		Carrying Value			Unrealized Gain (Loss)			
U.S. Treasury securities - maturities < 1 year	\$ 188,689	\$	188,733	\$	188,733	\$	44		
U.S. Treasury securities - maturities > 1 year	\$ 15,256	\$	15,255	\$	15,255	\$	(1)		
Total	\$ 203,945	\$	203,988	\$	203,988	\$	43		

#### 6. Licensing and Commercialization Agreement with Novartis Pharma AG

On May 19, 2014, the Company entered into a Licensing and Commercialization Agreement with Novartis Pharma AG (the "Novartis Agreement"). Under the Novartis Agreement, the Company granted Novartis exclusive rights under specified patent rights, know-how and trademarks controlled by the Company to manufacture, from bulk active pharmaceutical ingredient supplied by the Company, standalone Fovista products and products combining Fovista with an anti-VEGF product to which Novartis has rights in a co-formulated product, for the treatment, prevention, cure or control of any human disease, disorder or condition of the eye, and to develop and commercialize those licensed products in all countries outside of the United States (the "Novartis Territory"). The Company has agreed to use commercially reasonable efforts to complete its ongoing pivotal Phase 3 clinical program for Fovista and Novartis has agreed to use commercially reasonable efforts to develop a standalone Fovista product and a co-formulated product containing Fovista and an anti-VEGF product to which Novartis has rights, as well as a pre-filled syringe presentation of such products and to use commercially reasonable efforts, subject to obtaining marketing approval, to commercialize licensed products in the Novartis Territory in accordance with agreed development and marketing plans. Novartis has also granted the Company options, subject to specified limitations, and to the extent such rights are controlled by Novartis, to obtain exclusive rights from Novartis to develop and commercialize in the United States the co-formulated and pre-filled syringe products developed by Novartis. The Company and Novartis have each granted the other options, subject to specified limitations, to obtain access to study data from certain clinical trials of licensed products that the Company or Novartis may conduct, including for use by the other in regulatory filings in its territory. The Company has agreed to exclusively supply Novartis, and Novartis has agreed to exclusively purchase from the Company, its clinical and commercial requirements for the bulk active pharmaceutical ingredient in Fovista for use in licensed products in the Novartis Territory. The Company has agreed not to commercialize any product comprising Fovista or any other anti-PDGF product in the ophthalmic field in the Novartis Territory.

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Novartis paid the Company a \$200.0 million upfront fee upon execution of Novartis Agreement. Novartis is also obligated to pay the Company up to an aggregate of \$130.0 million if the Company achieves specified patient enrollment milestones for its ongoing pivotal Phase 3 clinical program for Fovista, and up to an aggregate of an additional \$300.0 million upon achievement of specified regulatory approval milestones, including reimbursement approval, in certain countries in the Novartis Territory. In addition, Novartis has agreed to pay the Company up to an aggregate of an additional \$400.0 million if Novartis achieves specified sales milestones in the Novartis Territory. Novartis also is obligated to pay the Company royalties with respect to standalone Fovista products and combination Fovista products that Novartis successfully commercializes. The Company will receive royalties at a mid-thirties percentage of net sales of standalone Fovista products and a royalty of approximately equal value for sales of combination Fovista products. Such royalties are subject to customary deductions, credits, and reductions for lack of patent coverage or market exclusivity. Novartis's obligation to pay such royalties will continue on a licensed product-by-licensed product and country-by-country basis until Novartis's last actual commercial sale of such licensed product in such country.

Novartis has agreed to pay the Company's manufacturing costs plus a specified percentage margin for supplies of the bulk active pharmaceutical ingredient in Fovista that the Company supplies to Novartis. If the Company or Novartis exercises each of their respective rights to obtain access to study data from clinical trials conducted by the other party, the party exercising the option will be obligated to pay the other party's associated past development costs and share with such other party any future associated development costs. If the Company exercises its option to obtain Novartis-controlled rights to develop, manufacture and commercialize any co-formulated Fovista product in the United States, the Company will be obligated to pay a specified percentage of Novartis's associated past development costs and share with Novartis any future associated development costs. The Company and Novartis will also need to negotiate and agree on financial and other terms that would apply to such rights. If the Company exercises its option to obtain Novartis-controlled rights to develop and commercialize a pre-filled syringe product in the United States, the Company will be obligated to either enter into a supply agreement with Novartis under which the Company will pay Novartis its manufacturing cost plus a specified percentage margin for supplies of Fovista products in pre-filled syringes that Novartis supplies to the Company, or obtain supplies of products in pre-filled syringes from a third party manufacturer and pay Novartis a low single-digit percentage of the Company's net sales of such products.

The Company has retained control over the design and execution of its pivotal Phase 3 clinical program for Fovista and remains responsible for funding the costs of that program, subject to Novartis's responsibility to provide Lucentis, an anti-VEGF agent to which Novartis has rights in the Novartis Territory, for use in the Phase 3 trials in the Novartis Territory following the effective date of the Novartis Agreement. Novartis will have control over, and will be responsible for the costs of, all other clinical trials that may be required to obtain marketing approvals in the Novartis Territory for licensed products under the agreement. Novartis is also responsible for costs associated with co-formulation development, pre-filled syringe development and other development costs in the Novartis Territory, excluding regulatory filing fees in the European Union for the standalone Fovista product, for which the Company will be responsible.

The Novartis Agreement, unless earlier terminated by the Company or Novartis, will expire upon the expiration of Novartis's obligation to pay the Company royalties on net sales of licensed products. The Company and Novartis each may terminate the Novartis Agreement if the other party materially

breaches the agreement and does not cure such breach within a specified cure period, if the other party experiences any specified insolvency event, if the other party challenges or assists a third party in challenging the validity or enforceability of certain patent rights controlled by the terminating party, or if the parties are prevented in any manner that materially adversely affects the progression of the development or commercialization of licensed products for a specified period as a result of specified governmental actions. Novartis may terminate the Novartis Agreement at any time without cause, or within a specified period after a change in control of the Company, as defined in the Novartis Agreement, or for specified safety reasons, effective at the end of a specified period following Novartis's written notice to the Company of Novartis's election to terminate the agreement. The Company may also terminate the agreement if Novartis determines to seek marketing approval of an alternative anti-PDGF product in the Novartis Territory as more fully described below. If the Company elects to terminate the Novartis Agreement because specified governmental actions prevent the parties from materially progressing the development or commercialization of licensed products as described above, the Company will be required to pay a substantial termination fee, with the specific amount of such fee determined based on the effective date of the termination. Following any termination, all rights to Fovista that the Company granted to Novartis, including, without limitation, the right to commercialize standalone Fovista products in the Novartis Territory, will revert to the Company, Novartis will perform specified activities in connection with transitioning to the Company the rights and responsibilities for the continued development, manufacture and commercialization of the standalone Fovista product for countries in the Novartis Territory, and the parties will cooperate on an orderly wind down of development and commercia

Novartis has agreed to specified limitations on its ability to in-license, acquire or commercialize any anti-PDGF product that does not contain Fovista (an "Alternative Anti-PDGF Product") in the Novartis Territory and, to the extent Novartis develops, in-licenses or acquires such a product, to make such product available to the Company in the United States under specified option conditions. If the Company exercises its option, the Company will be obligated to make certain payments to Novartis, including

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specified milestone and royalty payments. The amounts of such payments will vary based on the product's stage of clinical development at the time the Company exercise its option, whether the product is a standalone or combination product and whether Novartis exercises an option to co-promote such product in the United States. If Novartis determines to seek marketing approval of an Alternative Anti-PDGF Product in the Novartis Territory, the Company will, subject to specified limitations, have the option to terminate the Novartis Agreement, convert Novartis's exclusive licenses into non-exclusive licenses, or elect to receive a royalty on sales of such product by Novartis. If the Company elects to terminate the Novartis Agreement, Novartis will, subject to specified limitations, be required to pay to the Company, certain payments based on achievement, with respect to such product, of the milestones that would have otherwise applied to licensed products under the Novartis Agreement.

Activities under the licensing and commercialization Novartis Agreement were evaluated under ASC 605-25, *Revenue Recognition—Multiple Element Arrangements* ("ASC 605-25") (as amended by ASU 2009-13, *Revenue Recognition* ("ASU 2009-13")) to determine if they represented a multiple element revenue arrangement. The Novartis Agreement includes the following deliverables: (1) an exclusive license to commercialize Fovista outside the United States (the "License Deliverable"); (2) the performance obligation to conduct research and development activities related to the Phase 3 Fovista clinical trials and certain Phase 2 trials for Fovista (the "R&D Activity Deliverable"); and (3) the Company's obligation to participate on the joint operating committee established under the terms of the Novartis Agreement and related subcommittees (the "Joint Operating Committee Deliverable"). Novartis has the right, subject to the certain approval rights of the Company, to sublicense the exclusive royalty-bearing license to commercialize Fovista in the Novartis Territory. The Company's obligation to provide access to clinical and regulatory information as part of the License Deliverable includes the obligation to provide access to all clinical data, regulatory filings, safety data and manufacturing data to Novartis which is necessary for commercialization of Fovista in the Novartis Territory. The R&D Activity Deliverable includes the right and responsibility for the Company to conduct the Phase 3 Fovista clinical program and other studies of Fovista in the Novartis Territory which are necessary or desirable for regulatory approval or commercialization of Fovista. The Joint Operating Committee Deliverable includes the obligation to participate in the Joint Operating Committee and related subcommittees at least through the first anniversary of regulatory approval in the European Union. All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC 6

The Novartis Agreement provides that, if the Company elects to terminate the Novartis Agreement because specified governmental actions prevent the parties from materially progressing the development or commercialization of licensed products as described above, the Company will be required to pay a substantial termination fee, with the specific amount of such fee determined based on the effective date of the termination. The Company has concluded that this termination provision constitutes a contingent event that is unknown at the inception of the agreement. As such, the Company has recorded the \$200.0 million upfront payment in deferred revenue, long-term until such time that the contingency related to this termination provision is resolved. The Company believes the enrollment milestones and certain of the regulatory milestones that may be achieved under the Novartis Agreement do not meet the recognition criteria within the definition of a milestone included in ASU 2010-17, *Revenue Recognition—Milestone Method*, and therefore, payments received for the achievement of the enrollment milestones in excess of the termination fee will be included in the allocable arrangement consideration and allocated to the deliverables based upon BESP using the relative selling price method.

The Company believes the remaining regulatory approval milestones that may be achieved under the Novartis Agreement are consistent with the definition of a milestone included in ASU 2010-17, *Revenue Recognition—Milestone Method*, and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when the applicable milestone is achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

#### 7. Royalty Agreement with Novo A/S

In May 2013, the Company entered into a Purchase and Sale Agreement with Novo A/S, which is referred to as the Novo Agreement and which provides for the Company to sell, and Novo A/S to purchase, the right, title, and interest in a portion of the revenues from the sale of (a) Fovista, (b) Fovista-Related Products, and (c) Other Products (each as defined in the Novo Agreement), calculated as low to mid-single digit percentages of net sales.

The Novo Agreement provides for up to three separate purchases for a purchase price of \$41.7 million each, at a first, second and third closing, for an aggregate purchase price of \$125.0 million. In each purchase, Novo A/S acquires rights to a low single digit percentage of net sales. If all royalty interests under the Novo Agreement are purchased, Novo A/S will have a right to receive royalties on net sales at a mid-single digit percentage.

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for the third purchase upon the satisfaction of certain triggers and conditions detailed in the Novo Agreement, none of which have occurred prior to the date of these financial statements.

The royalty payment period covered by the Novo Agreement begins on commercial launch and ends, on a product-by-product and country-by-country basis, on the latest to occur of (i) the 12th anniversary of the commercial launch, (ii) the expiration of certain patent rights and (iii) the expiration of the regulatory exclusivity for each product in each country.

Under the terms of the Novo Agreement, the Company is not required to reimburse or otherwise compensate Novo A/S through any means other than the agreed royalty entitlement. In addition, the Company does not, under the terms of the Novo Agreement, have the right or obligation to prepay Novo A/S in connection with a change of control of the Company or otherwise.

The proceeds from the first and second financing tranches under the Novo Agreement were recorded as a liability on the Company's Balance Sheet as of June 30, 2014, in accordance with ASC Topic 730, *Research and Development*. Because there is a significant related party relationship between the Company and Novo A/S, the Company is treating its obligation to make royalty payments under the Novo Agreement as an implicit obligation to repay the funds advanced by Novo A/S. As the Company makes royalty payments in accordance with the Novo Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which would result in a corresponding increase in the liability balance.

The Novo Agreement requires the establishment of a Joint Oversight Committee in the event that Novo A/S does not continue to have a representative on the Company's board of directors. The Joint Oversight Committee would have responsibilities that include "discussion and review" of all matters related to Fovista research, development, regulatory approval and commercialization, but there is no provision either implicit or explicit that gives the Joint Oversight Committee or its members decision-making authority.

Proceeds of \$41.7 million received in 2014 from Novo A/S under the Novo Agreement will be reported as revenue for income tax purposes in 2014.

#### 8. Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets 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. As of June 30, 2014 and December 31, 2013, the Company does not believe any material uncertain tax positions were present. Accordingly, interest and penalties have not been accrued due to an uncertain tax position and the fact the Company has reported tax losses since inception.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible, and impacted by the Company's ability to carryback losses to previous years in which the Company had taxable income. In connection with the \$41.7 million the Company received from Novo A/S in January 2014 and the \$200.0 million the Company received from Novartis in May 2014, a portion of which has been deferred for income tax purposes, the Company is currently projecting taxable income in 2014, after taking into account the utilization of its federal net operating losses totaling \$86.0 million from prior years. As such, the Company currently estimates that it will make income tax payments of approximately \$29.5 million during the second half of 2014. Due to the Company's history of losses and lack of other positive evidence to support taxable income after the 2014 tax year, the Company has recorded a valuation allowance against those deferred tax assets that are not expected to be realized.

Deferred tax assets relating to employee share-based compensation deductions were reduced to reflect exercises of non-qualified stock option grants and vesting of restricted stock. Although certain of these deductions were reported on the corporate tax returns and increased net operating losses, these related tax benefits were not recognized for financial reporting purposes. The Company has unrealized excess tax benefits related to stock based compensation costs of \$1.2 million that it expects to credit to stockholder's equity in future periods.

The Company's federal, state, and local net operating loss carryforwards of approximately \$86.0 million are expected to be utilized in 2014. Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or

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public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed a study to determine whether it had undergone an ownership change since the Company's inception. The Company concluded that it had not undergone an ownership change and the Company expects that it will have the ability to utilize its net operating loss carryforwards against taxable income in 2014.

#### 9. 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 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 U.S. Treasury 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.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

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 June 30, 2014:

		Fair Value Measurement Using						
	activ ide	oted prices in e markets for ntical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)				
Assets								
Investments in U.S. Treasury money market funds*	\$	62,007						
Investments in U.S. Treasury securities with maturities < three months*	\$	181,946						
Investments in U.S. Treasury securities with maturities < 1 year	\$	188,733						
Investments in U.S. Treasury securities with maturities > 1 year	\$	15,255						

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, 2013:

		F	air Value Measu	rement Usins	3		
	Quoted p active ma identica (Lev	rkets for l assets	Significan observable (Level	inputs		Significant unobservable inputs (Level 3)	
Assets							
Investments in U.S. Treasury money market funds*	\$	203,828	\$	_	\$		_

<sup>\*</sup> Investments in U.S. Treasury money market funds and U.S. Treasury securities with maturities less than three months are reflected in cash and cash equivalents in the accompanying Balance Sheets.

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#### 10. Stock Option and Compensation Plans

The Company adopted its 2007 Stock Incentive Plan (the "2007 Plan") for employees, directors and consultants for the purpose of advancing the interests of the Company stockholders by enhancing its ability to attract, retain and motivate persons who are expected to make important contributions to the Company. The 2007 Plan provided for the granting of stock option awards, restricted stock awards, and other stock-based and cash-based awards. Following the effectiveness of the 2013 Stock Incentive Plan described below in connection with the closing of the Company's initial public offering, the Company is no longer granting additional awards under the 2007 Plan.

In August 2013, the Company's board of directors adopted and the Company's stockholders approved the 2013 stock incentive plan (the "2013 Plan"), which became effective immediately prior to the closing of the Company's initial public offering. The 2013 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock-based awards. Upon effectiveness of the 2013 Plan, the number of shares of the Company's common stock that were reserved for issuance under the 2013 Plan was the sum of (1) such number of shares (up to approximately 3,359,641 shares) as is equal to the sum of 739,317 shares (the number of shares of the common stock then available for issuance under the 2007 Plan), and such number of shares of the Company's common stock that are subject to outstanding awards under the 2007 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right plus (2) an annual increase, to be added the first day of each fiscal year, beginning with the fiscal year ending December 31, 2014 and continuing until, and including, the fiscal year ending December 31, 2023, equal to the lowest of 2,542,372 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the fiscal year and an amount determined by its board of directors. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2013 Plan. However, incentive stock options may only be granted to employees of the Company.

In connection with the evergreen provisions of the 2013 Plan, the number of shares available for issuance under the 2013 Plan was increased by approximately 1,257,000 shares, effective as of January 1, 2014. As of June 30, 2014, the Company had approximately 3,851,000 stock options and approximately 25,000 restricted stock units outstanding under the 2013 Plan and approximately 499,000 shares available for grant under the 2013 Plan.

Cash proceeds from, and the aggregate intrinsic value of, stock options exercised during the three and six months ended June 30, 2014 and 2013, respectively, were as follows:

Three months ended June 30, Six months ended June 30,
---

	2	2014		2013		2014		2013
	_		_		_		_	
Cash Proceeds from options exercised	\$	289	\$	_	\$	300	\$	_
Aggregate intrinsic value of options exercised	\$	2,730	\$	_	\$	3,099	\$	_

A summary of the stock options outstanding and exercisable as of June 30, 2014 is as follows:

				As of June	30, 2014			
		Options O	utstan	ding	Options E	Exercisable		
Range of Exercise Prices	 Total Options Outstanding	Weighted Average Remaining Life (Years)		Weighted Average Exercise Price	Number Exercisable	_	Weighted Average Exercise Price	
\$0.12-\$10.03	1,711	7.3	\$	4.99	1,060	\$	3.07	
\$10.04-\$20.00	601	9.0	\$	13.37	79	\$	13.22	
\$20.01-\$30.00	185	9.3	\$	25.75	3	\$	27.63	
\$30.01-\$43.90	1,354	9.6	\$	31.93	15	\$	34.20	
	3,851				1,157			
Aggregate Intrinsic Value	\$ 98,373				\$ 44,077			

In connection with stock option awards granted to employees, the Company recognized share-based compensation expense of approximately \$2.8 million and \$0.3 million for the three months ended June 30, 2014 and 2013, respectively. In connection with stock option awards granted to employees, the Company recognized share-based compensation expense of approximately \$5.3 million

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and \$0.4 million for the six months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, there was approximately \$36.0 million of unrecognized compensation costs, net of estimated forfeitures, related to stock option awards to employees, which are expected to be recognized over a remaining weighted average period of 3.3 years.

In connection with stock options awards granted to consultants, the Company recognized approximately \$0.3 million and \$0.1 million, in share-based compensation expense during the three months ended June 30, 2014 and 2013, respectively. In connection with stock options awards granted to consultants, the Company recognized approximately \$0.5 million and \$0.1 million, in share-based compensation expense during the six months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, there was approximately \$3.7 million of unrecognized compensation costs, net of estimated forfeitures, related to stock option award granted to consultants which are expected to be recognized over a remaining weighted average period of 3.2 years.

In connection with restricted stock units granted to employees, the Company recognized share-based compensation of approximately \$0.1 million in the three and six month periods ended June 30, 2014. The Company did not recognize any share-based compensation expense related to restricted stock units during the three and six month periods ended June 30, 2013. As of June 30, 2014, there was approximately \$0.7 million of unrecognized compensation costs, net of estimated forfeitures, related to restricted stock units granted to employees to be recognized over a remaining weighted average period of 1.8 years.

#### 11. Property and Equipment

Property and equipment at June 30, 2014 and December 31, 2013 were as follows:

	Useful Life (Years)	June	30, 2014	Dece	mber 31, 2013
Manufacturing equipment	7-10	\$	184	\$	_
Computer and other office equipment	5		291	\$	85
Furniture and fixtures	7		478		117
Leasehold improvements	3-5		91		
			1,044		202
Accumulated depreciation and amortization			(218)		(175)
Property and equipment, net		\$	826	\$	27

For the three months ended June 30, 2014 and 2013, depreciation expense was \$31 thousand and \$3 thousand, respectively. For the six months ended June 30, 2014 and 2013, depreciation expense was \$43 thousand and \$10 thousand, respectively.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2013 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2014. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. (Risk Factors) of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

We are a biopharmaceutical company specializing in the development of novel therapeutics to treat diseases of the back of the eye, with a focus on developing therapeutics for age-related macular degeneration, or AMD. Our most advanced product candidate is Fovista, which is in Phase 3 clinical development for use in combination with anti-VEGF drugs that represent the current standard of care for the treatment of wet AMD. We have completed one Phase 1 and one Phase 2b clinical trial of Fovista administered in combination with the anti-VEGF drug Lucentis. We are also developing our product candidate Zimura, with an initial focus on the treatment of patients with geographic atrophy, a severe form of dry AMD.

We have initiated a pivotal Phase 3 clinical program for Fovista, which consists of three separate Phase 3 clinical trials to evaluate the safety and efficacy of Fovista administered in combination with anti-VEGF drugs for the treatment of wet AMD compared to anti-VEGF monotherapy and are actively enrolling patients in these trials. Two of these trials are evaluating Fovista in combination with Lucentis and the other is evaluating Fovista in combination with each of Eylea or Avastin. We plan to enroll a total of 1,866 patients at more than 225 centers internationally across the three trials.

Based on our estimates regarding patient enrollment, we expect to have initial, top-line data from our Phase 3 clinical program for Fovista available in 2016. If the results of this Phase 3 clinical program are favorable, we plan to submit applications for marketing approval for Fovista in the United States and, together with our commercialization partner Novartis, in the European Union before the end of 2016. We have also initiated a Phase 2a open label study designed to investigate the potential effect of administration of Fovista in combination with anti-VEGF therapy in reducing the formation of subretinal fibrosis in wet AMD patients. We also plan to initiate additional Phase 2 clinical trials in the second half of 2014, which are intended to further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs. We are also planning additional clinical trials to assess the potential therapeutic benefit of Fovista in other ophthalmic conditions.

On May 19, 2014, we entered into a Licensing and Commercialization Agreement with Novartis Pharma AG, which we refer to as the Novartis Agreement. Under the Novartis Agreement, we granted Novartis exclusive rights under specified patent rights, know-how and trademarks controlled by us to manufacture, from bulk active pharmaceutical ingredient supplied by us, standalone Fovista products and products combining Fovista with an anti-VEGF product to which Novartis has rights in a co-formulated product, for the treatment, prevention, cure or control of any human disease, disorder or condition of the eye, and to develop and commercialize those licensed products in all countries outside of the United States, which we refer to as the Novartis Territory. We have agreed to use commercially reasonable efforts to complete our ongoing pivotal Phase 3 clinical program for Fovista and Novartis has agreed to use commercially reasonable efforts to develop a standalone Fovista product and a co-formulated product containing Fovista and an anti-VEGF to which Novartis has rights, as well as a pre-filled syringe presentation of such products and to use commercially reasonable efforts, subject to obtaining marketing approval, to commercialize licensed products in the Novartis Territory in accordance with agreed development and marketing plans.

Novartis paid us a \$200.0 million upfront fee upon execution of the Novartis Agreement. Novartis is also obligated to pay us up to an aggregate of \$130.0 million if we achieve specified patient enrollment milestones for our ongoing pivotal Phase 3 clinical program for Fovista, and up to an aggregate of an additional \$300.0 million upon achievement of specified marketing approval milestones in certain countries in the Novartis Territory. In addition, Novartis has agreed to pay us up to an aggregate of an additional \$400.0 million if Novartis achieves specified sales milestones in the Novartis Territory. Novartis also is obligated to pay us royalties with respect to standalone Fovista products and combination Fovista products that Novartis successfully commercializes. We will receive royalties at a mid-thirties percentage of net sales of standalone Fovista products and a royalty of approximately equal value for sales of combination Fovista products. Such royalties are subject to customary deductions, credits, and reductions for lack of patent coverage or market exclusivity. Novartis's obligation to pay such royalties will continue on a licensed product-by-licensed product and country-by-country basis until Novartis's last actual sale of such licensed product in such country.

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We have retained control over the design and execution of our pivotal Phase 3 clinical program for Fovista and remain responsible for funding the costs of that program, subject to Novartis's responsibility to provide Lucentis, an anti-VEGF agent to which Novartis has rights in the Novartis Territory, for use in the Phase 3 trials in the Novartis Territory following the effective date of the Novartis Agreement. Novartis will have control over, and will be responsible for the costs of, all other clinical trials that may be required to obtain marketing approvals in the Novartis Territory for licensed products under the agreement. Novartis is also responsible for costs associated with co-formulation development, pre-filled syringe development and other development costs in the Novartis Territory, but excluding regulatory filing fees in the European Union for the standalone Fovista product, for which we will be responsible.

We also plan to initiate a Phase 2/3 clinical trial to evaluate the safety and efficacy of Zimura monotherapy in patients with geographic atrophy in late 2014 or early 2015. We are also developing Zimura and Fovista to be administered in combination with anti-VEGF drugs for the treatment of a subpopulation of wet AMD patients who do not respond adequately to treatment with anti-VEGF monotherapy or for whom anti-VEGF monotherapy fails and who are believed to have complement mediated inflammation. We plan to initiate a Phase 2 clinical trial of Zimura and Fovista administered in combination with an anti-VEGF drug in this second indication in 2015.

We were incorporated and commenced active operations in 2007. Our operations to date have been limited to organizing and staffing our company, acquiring rights to product candidates, business planning, raising capital and developing Fovista, Zimura and other product candidates. We acquired our rights to Fovista from (OSI) Eyetech, Inc., or Eyetech, in July 2007. The acquisition included an assignment of license rights and obligations under an agreement with Archemix Corp. We have licensed rights to our product candidate Zimura from Archemix Corp. Since inception, we have incurred significant operating losses. Our net loss was \$73.2 million for the six months ended June 30, 2014, and \$51.1 million for the year ended December 31, 2013. As of June 30, 2014, we had an accumulated deficit of \$256.2 million. We have not generated any revenues from product sales and have financed our operations primarily through private placements of our preferred stock, venture debt borrowings, funding under our royalty purchase and sale agreement with Novo A/S, our initial public offering, which we closed in September 2013, our follow-on public offering of common stock, which we closed in February 2014, and the Novartis Agreement. We received net proceeds from the initial public offering of \$175.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. We received net proceeds from the follow-on public offering of \$55.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. We have received \$83.3 million of royalty funding to date under our royalty purchase and sale agreement with Novo A/S, which we refer to as the Novo Agreement. We also received an upfront payment of \$200.0 million from Novartis upon the execution of the Novartis Agreement. In connection with the receipt of the payment from Novartis, we made a milestone payment in June 2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million during the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

We initiated our pivotal Phase 3 clinical program for Fovista in August 2013. We expect our expenses to continue to increase substantially, particularly as we continue the development of Fovista in our Phase 3 clinical program for the treatment of wet AMD. We plan to enroll a total of 1,866 patients for this program, most of which we expect to enroll in 2014 and 2015. In addition, we also expect our expenses to increase as we further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need and pursue the development of Zimura, with an initial focus on the treatment of geographic atrophy, a severe form of dry AMD, and pursue an additional planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation. We expect these expenses to increase as patient enrollment increases in these clinical trials. In addition, if we obtain marketing approval for Fovista, Zimura or any other product candidate that we may develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we are incurring and will continue to incur additional costs associated with operating as a public company, hiring additional personnel and expanding our facilities. These costs include significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Moreover, additional rules and regulations applicable to public companies will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Our ability to become and remain profitable depends on our ability to generate revenue in excess of our expenses. We do not expect to generate and maintain significant revenue unless, and until, we obtain marketing approval for, and commercialize, Fovista, Zimura or other product candidates that we may develop. We may be unsuccessful in our efforts to develop and commercialize these 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. Our capital requirements will also depend on many other factors, including whether we pursue the acquisition or in-licensing and subsequent development of additional product candidates. We may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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#### **Financial Operations Overview**

#### Revenue

To date, we have not generated any revenues from product sales. In the future, we may generate revenue from a combination of product sales and license fees, milestone payments and research and development activity-related payments and royalties in connection with the Novartis Agreement. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of certain milestone and other payments, if any, that we may receive from Novartis and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from products sales until 2017 at the earliest. If we fail to complete the development of Fovista, Zimura or other product candidates we may develop, in a timely manner or obtain regulatory approval for them, our ability to generate future revenue and our results of operations and financial position, would be materially adversely affected.

#### Research and Development Expenses

Research and development expenses consist of costs associated with the development and clinical testing of Fovista and Zimura. Our research and development expenses consist of:

- · external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, and other vendors, contract manufacturing organizations and consultants; and
- · employee-related expenses, including salaries, benefits, travel and share-based compensation expense.

All research and development costs are charged to operations as incurred in accordance with Financial Accounting Standards Board Accounting Standards Codification, or ASC, 730 Topic, *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.

To date, the large majority of our research and development work has been related to Fovista, Zimura and a product candidate, volociximab, that we were previously developing for the treatment of wet AMD. We licensed rights to volociximab in January 2008 and then terminated the license agreement in May 2012 to focus on the development of Fovista. We anticipate that our research and development expenses will increase substantially in connection with our ongoing activities, particularly as we continue the development of and seek marketing approval for Fovista, Zimura and, possibly, other product candidates.

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 functional area and by compound, as shown below.

The following table summarizes our research and development expenses for the three and six months ended June 30, 2014 and 2013:

	Three months	ended Ju	ne 30,	Six months e	nded Ju	ne 30,
	 2014		2013	2014		2013
	 (in tho	usands)		 (in tho	usands)	<u> </u>
Fovista	\$ 29,970	\$	3,177	\$ 40,678	\$	4,854
Zimura	755		4	999		7
Personnel related	2,013		900	3,758		1,538
Share-based compensation	1,945		262	3,607		330
Other	24		2	42		5
	\$ 34,707	\$	4,345	\$ 49,084	\$	6,734

As of June 30, 2014, we had cash, cash equivalents, and marketable securities of \$452.5 million, which includes the \$200.0 million upfront payment that we received upon the execution of the Novartis Agreement. We also had \$318.7 million in total liabilities as of June 30, 2014, including long-term liabilities of \$283.3 million relating to the Novo Agreement and deferred revenue associated with the Novartis Agreement. In connection with the receipt of the payment from Novartis, we made a milestone payment in June

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2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million in the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations and capital expenditure requirements, as currently planned, through the end of 2017. We expect to obtain initial, top-line data from our Phase 3 clinical program for Fovista in 2016. Our capital requirements will depend on many factors, including the success of our development and commercialization of our product candidates and whether we pursue the acquisition or in-licensing and subsequent development of additional product candidates.

We expect to spend significant additional funds on our Phase 3 clinical program for Fovista, our other planned clinical programs, including additional clinical trials to further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet medical need, an additional planned clinical trial evaluating Zimura for the treatment of geographic atrophy and pursue an additional planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation, and for general corporate purposes and working capital. Costs related to our clinical programs could exceed our expectations if we experience delays in our clinical trials, including because of the timing of our patient enrollment, the availability and costs of drug supply for our clinical trials or for other reasons. Our costs will also increase if we increase investigator fees for our clinical trials or expand the scope of our clinical trials and programs, or change the geographic mix of sites at which patients are enrolled, or increase other corporate or licensing activities, or staffing.

Our current Phase 3 clinical program for Fovista is expected to continue through at least 2017, and substantial expenditures to complete the Phase 3 clinical program will be required after the receipt of initial, top-line data and to fund our other development programs. Moreover, we are at the early stages of formulating our clinical development plan for Zimura. We expect the clinical development of Zimura will continue for at least the next several years. At this time, we cannot reasonably estimate the remaining costs necessary to complete the clinical development of either Fovista or Zimura, complete process development and manufacturing scale-up activities associated with Fovista and Zimura and seek marketing approval for Fovista or Zimura, or the nature, timing or costs of the efforts necessary to complete the development of any other product candidate we may develop.

The successful development of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- · the scope, rate of progress and expense of our research and development activities;
- the potential benefits of our product candidates over other therapies;
- · our and our commercialization partner's ability to market, commercialize and achieve market acceptance for any of our product candidates;
- · clinical trial results;
- the terms and timing of regulatory approvals; 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 Fovista, Zimura or any other product candidate we may develop could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if regulatory authorities were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of Fovista or any other product candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

#### 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, finance and business development functions. Other general and administrative expenses include facility costs and professional fees for legal, patent, consulting and accounting services.

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We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development and commercialization activities and as a result of increased headcount, including management personnel to support our clinical and manufacturing activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors.

#### **Interest Income**

Our cash, cash equivalents and marketable securities are invested primarily in U.S. Treasury money market funds and U.S. Treasury securities, which generate a small amount of interest income. We expect to continue that investment philosophy as we obtain more financing proceeds.

#### **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. 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 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 fees paid or payable to CROs and other vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct research and development 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 research and development 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.

#### Revenue Recognition

To date, we have not generated any revenue. In the future, we may generate revenues from a combination of products sales and license fees, milestone payments and research and development activity-related payments and royalties in connection with the Novartis Agreement. The terms of this agreement and other potential collaboration or commercialization agreements we may enter into generally contain multiple elements, or deliverables, which may include (i) licenses, or options to obtain licenses, to our technology, (ii) research and development activities to be performed on behalf of the collaborative partner, and (iii) in certain cases, services in connection with the manufacturing of pre-clinical and clinical material. Payments to us under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

When evaluating multiple element arrangements, we consider whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated

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among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE is available. Determining the best estimate of selling price for a deliverable requires significant judgment. We use BESP to estimate the selling price for licenses to our proprietary technology, since we often do not have VSOE or TPE of selling price for these deliverables. In those circumstances where we utilize BESP to determine the estimated selling price of a license to our proprietary technology, we consider market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating our best estimate of selling price, we evaluate whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

We received an up-front, non-refundable payment of \$200.0 million in connection with the Novartis Agreement, which has not been recorded as revenue due to certain contingencies associated with the payment. When management believes the license to its intellectual property and products has standalone value, we generally recognize revenue attributed to the license upon delivery. When management believes such a license does not have stand-alone value from the other deliverables to be provided in the arrangement, we generally recognize revenue attributed to the license on a straight-line basis over our contractual or estimated performance period, which is typically the term of our research and development obligations. If management cannot reasonably

estimate when our performance obligation ends, then revenue is deferred until management can reasonably estimate when the performance obligation ends. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

At the inception of arrangements that include milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

We aggregate our milestones into three categories: (i) clinical and development milestones, (ii) regulatory milestones, and (iii) commercial milestones. Clinical and development milestones are typically achieved when a product candidate advances into a defined phase of clinical research or completes such phase. Regulatory milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other global regulatory authorities. For example, a milestone payment may be due to us upon the FDA's acceptance of an NDA. Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount.

Revenues from clinical and development and regulatory milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, are recognized upon successful accomplishment of the milestones. With regards to the Novartis Agreement, we have concluded that the clinical and development milestones and certain regulatory milestones are not substantive and that the regulatory approval milestones pursuant to the Novartis Agreement are substantive. Milestones payments received that are not considered substantive are included in the allocable arrangement consideration and are recognized as revenue in proportion to the relative-selling price allocation established at the inception of the arrangement. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

#### Royalty Purchase Liability

The proceeds from the first and second financing tranches under the Novo Agreement have been recorded as a liability on our balance sheet in accordance with ASC Topic 730, *Research and Development*. Because there is a significant related party relationship between us and Novo A/S, we are treating our obligation to make royalty payments under the Novo agreement as an implicit obligation to repay the funds advanced by Novo A/S, and thus have recorded the proceeds as a liability on our balance sheet. As we make royalty payments to Novo A/S in accordance with the Novo agreement, we will reduce the liability balance. At the time that

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such royalty payments become probable and estimable, and if such amounts exceed the liability balance, we will impute interest accordingly on a prospective basis based on such estimates, which would result in a corresponding increase in the liability balance.

#### **Share-Based Compensation**

We account for all share-based compensation payments issued to employees, directors, and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

We apply the fair value recognition provisions of ASC Topic 718, *Compensation—Stock Compensation*. Determining the amount of share-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. We recognize share-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and the expected dividend yield of our common stock. As a new public company, we do not have sufficient history to estimate the volatility of our common stock price or the expected life of the options. We calculate expected volatility based on reported data for similar publicly traded companies for which historical information is available and will continue to do so until the historical volatility of our common stock is sufficient to measure expected volatility for future option grants.

We use the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. 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 six months ended June 30, 2014 and 2013:

	Three months	ended June 30,	Six months en	nded June 30,
	2014 2013		2014	2013
Expected common stock price volatility	77%	82%	84%	82%
Risk-free interest rate	1.61%-2.48%	0.89%-2.48%	1.61%-2.48%	0.89%-2.48%
Expected term of options (years)	6.5	6.1	6.2	6.1

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Through June 30, 2014, actual forfeitures have not been material.

Share-based compensation expense for equity grants to employees and non-employees was \$3.2 million for the three months ended June 30, 2014 and \$0.4 million for the three months ended June 30, 2013. Share-based compensation expense for equity grants to employees and non-employees was \$5.9 million for the six months ended June 30, 2014 and \$0.5 million for the six months ended June 30, 2013. As of June 30, 2014, we had \$40.4 million of total unrecognized share-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 3.2 years. We expect our share-based compensation for our share-based awards to employees and non-employees to increase as a result of recognizing our existing unrecognized share-based compensation for awards that will vest and as we issue additional share-based awards to attract and retain our employees.

For the three and six months ended June 30, 2014 and 2013, we allocated share-based compensation as follows:

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	Three months	ended Ju	une 30,	 Six months en	nded Ju	me 30,
	2014		2013	2014		2013
Research and development	\$ 1,945	\$	262	\$ 3,607	\$	330
General and administrative	1,238		90	2,305		130
Total	\$ 3,183	\$	352	\$ 5,912	\$	460

#### **Income Taxes**

As of December 31, 2013, we had approximately \$86.0 million of federal net operating loss carry-forwards. We also had federal and state research and development tax credit carry-forwards of approximately \$3.0 million available to offset future taxable income.

In January 2014, we received \$41.7 million from Novo A/S under the Novo Agreement, which will be reported as revenue for income tax purposes. In May 2014, we received \$200.0 million from Novartis in connection with Novartis Agreement, a portion of which will be reported as revenue for income tax purposes. As a result of these payments, and after taking into account the utilization of our federal net operating loss carry-forwards, we are projecting taxable income for the 2014 tax year. These projections are based upon estimates, which could change in the future. We currently estimate that we will be required to make income tax payments of approximately \$29.5 million relating to the payments received from Novo and Novartis in 2014. In addition, we expect that the valuation allowance on certain of our deferred tax assets will be released, where appropriate. See Note 8 to our financial statements in Part I-Item 1 of this Quarterly Report on form 10-Q for further information regarding our expectations with respect to our income tax provision.

#### **JOBS Act**

As an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, we have been entitled to take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to delay our adoption of such new or revised accounting standards. As a result of this election, our financial statements may not be comparable to the financial statements of other public companies. Commencing in January 1, 2015, we will no longer qualify for such status and we will need to comply with all new or revised accounting standards applicable to other public companies. We do not expect this prospective change in status to have a material impact on our 2015 financial position or results of operations.

#### **Results of Operations**

#### Comparison of Three Month Periods Ended June 30, 2014 and 2013

	Three months ended June 30,						
		2014 (in thou	cande)	2013	Inc	crease (Decrease)	
Statement of Operations Data:		(III tiloti	sanusj				
Revenue	\$	_	\$	_	\$	_	
Operating Expenses:							
Research and development		34,707		4,345		30,362	
General and administrative		7,570		3,242		4,328	
Total operating expenses		42,277		7,587		34,690	
Loss from operations		(42,277)		(7,587)		34,690	
Interest income (expense)		72		(1,097)		(1,169)	
Loss on extinguishment of debt		_		(1,196)		(1,196)	
Other loss		_		(126)		(126)	
Net loss before income tax benefit		(42,205)		(10,006)		32,199	
Income tax provision		(10,294)				10,294	
Net loss		(52,499)		(10,006)		42,493	
Add: accretion of preferred stock dividends		_		(1,858)		(1,858)	
Net loss attributable to common stockholders	\$	(52,499)	\$	(11,864)	\$	40,635	

#### Revenue

We did not recognize any revenue for the three months ended June 30, 2014 or for the three months ended June 30, 2013.

#### Research and Development Expenses

Our research and development expenses were \$34.7 million for the three months ended June 30, 2014, an increase of \$30.4 million compared to \$4.3 million for the three months ended June 30, 2013. The increase was primarily due to a milestone payment of \$19.8 million that we made in June 2014 in connection with the Novartis Agreement and costs associated with our Fovista Phase 3 clinical program, including clinical trial costs and the costs to manufacture Fovista for the trials as we continue to progress the Fovista Phase 3 clinical program. Other contributing factors include increased personnel costs associated with additional management and research and development staffing, including share-based compensation expense. We initiated our pivotal Phase 3 clinical program for Fovista in August 2013.

#### General and Administrative Expenses

Our general and administrative expenses for the three months ended June 30, 2014 were \$7.6 million, an increase of \$4.3 million compared to \$3.2 million for the three months ended June 30, 2013. The increase was primarily due to an increase in personnel costs, including additional management and corporate staffing to support our public company infrastructure and increased share-based compensation, and professional services and consulting fees.

#### Interest Income (Expense), net

Net interest income for the three months ended June 30, 2014 was \$0.1 million compared to net interest expense of \$1.1 million for the three months ended June 30, 2013. Net interest income earned during the three months ended June 30, 2014 was a result of a significant increase in our cash, cash equivalents and marketable securities average balances during the three months ended June 30, 2014 as compared to the three months ended June 30, 2013. The amounts recorded in the three months ended June 30, 2013 were related to interest associated with our venture debt facility that we entered into in June 2012. The debt facility was paid off in May 2013 and as such, there was no corresponding interest expense during the three months ended June 30, 2014.

#### Other Loss

There was no other loss recorded for the three months ended June 30, 2014 compared to other loss of \$0.1 million for the three months ended June 30, 2013. Amounts recorded as other loss were due to the change in fair value of the preferred stock warrant liability recorded in the second quarter of 2013. Upon completion of our initial public offering in September 30, 2013, the preferred stock warrants were converted to common stock warrants and are now treated as permanent equity.

#### **Provision for Income Taxes**

The provision for income taxes recorded for the three months ended June 30, 2014 was \$10.3 million. This primarily relates to an increase in projected taxable income for 2014, which was a result of payments we received from Novartis and Novo A/S totaling approximately \$241.7 million. For the three months ended June 30, 2013, we did not record a provision for income taxes due to our significant operating losses.

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#### Comparison of Six Month Periods Ended June 30, 2014 and 2013

	 Six months en				
	 2014		2013	Increa	se (Decrease)
	(in thou	sands)			
Statement of Operations Data:					
Revenue	\$ _	\$	_	\$	_
Operating Expenses:					
Research and development	49,084		6,734		42,350
General and administrative	 13,919		4,980		8,939
Total operating expenses	 63,003		11,714		51,289
Loss from operations	 (63,003)		(11,714)		51,289
Interest income (expense)	116		(1,454)		(1,570)
Loss on extinguishment of debt	_		(1,196)		(1,196)
Other loss	_		(260)		(260)
Net loss before income tax benefit	(62,887)		(14,624)		48,263
Income tax provision	(10,294)		<u> </u>		10,294
Net loss	(73,181)		(14,624)		58,557
Add: accretion of preferred stock dividends	_		(3,600)		(3,600)
Net loss attributable to common stockholders	\$ (73,181)	\$	(18,224)	\$	54,957

#### Revenue

We did not recognize any revenue for the six months ended June 30, 2014 or for the six months ended June 30, 2013.

#### Research and Development Expenses

Our research and development expenses were \$49.1 million for the six months ended June 30, 2014, an increase of \$42.4 million compared to \$6.7 million for the six months ended June 30, 2013. The increase was primarily due to a milestone payment of \$19.8 million that we made in June 2014 in

connection with the Novartis Agreement and costs associated with our Fovista Phase 3 clinical program, including clinical trial costs and the costs to manufacture Fovista for the trials as we continue to progress the Fovista Phase 3 clinical program. Other contributing factors include increased personnel costs associated with additional management and research and development staffing, including share-based compensation expense. We initiated our pivotal Phase 3 clinical program for Fovista in August 2013.

#### General and Administrative Expenses

Our general and administrative expenses for the six months ended June 30, 2014 were \$13.9 million, an increase of \$8.9 million compared to \$5.0 million for the six months ended June 30, 2013. The increase was primarily due to an increase in personnel costs, including additional management and corporate staffing to support our public company infrastructure and increased share-based compensation, and professional services and consulting fees.

#### Interest Income (Expense), net

Net interest income for the six months ended June 30, 2014 was \$0.1 million compared to net interest expense of \$1.5 million for the six months ended June 30, 2013. Net interest income earned during the six months ended June 30, 2014 was a result of a significant increase in our cash, cash equivalents and marketable securities average balances during the six months ended June 30, 2014 as compared to the six months ended June 30, 2013. The amounts recorded in the six months ended June 30, 2013 were related to interest associated with our venture debt facility that we entered into in June 2012. The debt facility was paid off in May 2013 and as such, there was no corresponding interest expense during the six months ended June 30, 2014.

#### Other Loss

There was no other loss recorded for the six months ended June 30, 2014 compared to other loss of \$0.3 million for the six months ended June 30, 2013. Amounts recorded as other loss were due to the change in fair value of the preferred stock warrant liability recorded in the first half of 2013. Upon completion of our initial public offering in September 30, 2013, the preferred stock warrants were converted to common stock warrants and are now treated as permanent equity.

#### **Provision for Income Taxes**

The provision for income taxes recorded for the three months ended June 30, 2014 was \$10.3 million. This primarily relates to an increase in projected taxable income for 2014, which was a result of payments we received from Novartis and Novo A/S totaling approximately \$241.7 million. For the six months ended June 30, 2013, we did not record a provision for income taxes due to our significant operating losses.

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#### **Liquidity and Capital Resources**

#### Sources of Liquidity

Since inception, we have financed our operations primarily through private placements of our preferred stock, venture debt borrowings, funding we received under the Novo Agreement, our initial public offering, which we closed on September 30, 2013, our follow-on public offering of common stock, which we completed in February 2014, and funds we received under the Novartis Agreement. In September 2013, we issued and sold an aggregate of 8,740,000 shares of common stock in our initial public offering at a public offering price of \$22.00 per share. We received net proceeds from the initial public offering of \$175.6 million. The Novo Agreement, which is described in more detail below, provides for financing of up to \$125.0 million in the aggregate in return for the sale to Novo A/S of royalty interests in worldwide sales of Fovista. We received an aggregate of \$83.3 million of this royalty financing in separate tranches in May 2013 and January 2014. Our receipt of the final tranche of financing is subject to enrollment of specified numbers of patients in our Phase 3 clinical trials of Fovista and our satisfying additional closing conditions and other obligations. In May 2013, we issued and sold an aggregate of 6,666,667 shares of our series C preferred stock at a price per share of \$2.50, for an aggregate purchase price of \$16.7 million. In August 2013, we issued and sold an aggregate of 13,333,333 additional shares of our series C preferred stock to the same purchasers at a price per share of \$2.50, for an aggregate purchase price of \$33.3 million. In February 2014, we issued and sold 1,900,000 shares of common stock and selling shareholders sold 728,571 shares of common stock in a follow-on public offering at a public offering price of \$31.50 per share. We received net proceeds of \$55.4 million from the follow-on offering.

In May 2014, we received an upfront payment of \$200.0 million in connection with the Novartis Agreement for the rights to commercialize Fovista, a product candidate currently in Phase 3 clinical trials, outside the United States. Novartis is also obligated to pay us up to an aggregate of \$130.0 million if we achieve specified patient enrollment milestones for its ongoing pivotal Phase 3 clinical program for Fovista. In connection with the receipt of the upfront payment from Novartis, we made a milestone payment in June 2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million during the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

#### Cash Flows

As of June 30, 2014, we had cash, cash equivalents and marketable securities totaling \$452.5 million. We also had \$318.7 million in total liabilities as of June 30, 2014, including long-term liabilities of \$283.3 million relating to the Novo Agreement and deferred revenue associated with Novartis Agreement. We primarily invest our cash, cash equivalents and marketable securities in U.S. Treasury securities and money market funds that invest in U.S. Treasury securities.

The following table shows a summary of our cash flows for the six months ended June, 2014 and 2013:

	Six months	ended Jui	ne,
	 2014	2013	
	(in thou	sands)	
Net cash (used in) provided by:			
Operating Activities	\$ 144,948	\$	(10,435)
Investing Activities	(205,666)		_

Financing Activities	98,620	45,984
Net change in cash and cash equivalents	\$ 37,902	\$ 35,549

#### **Cash Flows from Operating Activities**

Net cash provided by operating activities of \$144.9 million for the six months ended June 30, 2014 relates primarily to the upfront payment of \$200.0 million in connection with the Novartis Agreement, offset by (i) a milestone payment in June 30, 2014 of approximately \$19.8 million that we paid under one of our agreements in connection with the Novartis Agreement and (ii) costs we have incurred in our efforts to advance Fovista into Phase 3 clinical trials, including increased spending on Phase 3 clinical trial costs and manufacturing activity for Fovista, as well as increased general and administrative expenses. Net cash used in operating activities in prior periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital.

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In August 2013, we initiated our pivotal Phase 3 clinical program for Fovista that consists of three separate clinical trials. Two of these trials were initiated in the third quarter of 2013 and the third trial was initiated in the first quarter of 2014. We expect our significant cash outflows to continue to increase substantially for the foreseeable future, particularly as our patient enrollment increases in our Phase 3 clinical program and as we continue the development of and seek marketing approval for Fovista, Zimura and, possibly, other product candidates we may develop.

#### Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2014 relates primarily to the purchase of marketable securities totaling \$244.8 million offset by market security maturities of \$40.0 million. Also contributing to our cash used in investing activities for this period were capital expenditures associated with our new office facilities in New York, New York and Princeton, New Jersey. We did not use any cash for investing activities for the six months ended June 30, 2013.

#### Cash Flows from Financing Activities

Net cash provided by financing activities was \$98.6 million for the six months ended June 30, 2014 and \$46.0 million for the six months ended June 30, 2013. Net cash provided by financing activities for the six months ended June 30, 2014 consisted primarily of proceeds of \$55.4 million from our follow-on public offering in February 2014, and proceeds of \$41.7 million from the Novo Agreement in January 2014. Net cash provided by financing activities for the six months ended June 30, 2013 related primarily to proceeds of \$41.7 million from the Novo Agreement in May 2013.

#### **Funding Requirements**

Our product candidates, Fovista and Zimura, are still in clinical development. We expect our expenses to increase substantially as compared to prior periods, particularly as we continue the development of Fovista in our Phase 3 clinical program for the treatment of wet AMD. We initiated our pivotal Phase 3 clinical program for Fovista in August 2013. We plan to enroll a total of 1,866 patients for this program, most of which we expect to enroll in 2014 and 2015. In addition, we also expect our expenses to increase as we further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet medical need and pursue the development of Zimura, with an initial focus on the treatment of geographic atrophy, a severe form of dry AMD, and pursue a planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation. We expect our expenses to increase as patient enrollment increases in these clinical trials. In addition, if we obtain marketing approval for Fovista, we expect to incur significant commercialization expenses in the United States related to product sales, marketing, distribution and manufacturing. Outside the United States, our partner Novartis is responsible for these commercialization expenses. Also, if we obtain marketing approval for Zimura or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we are incurring and expect to continue to incur additional costs associated with being a public company, including legal, compliance, accounting and investor and public relations expenses as well as increased insurance premiums. We are party to agreements, specifically an asset acquisition agreement with OSI (Eyetech), Inc., which agreement is now held by OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC, and license agreements with Archemix Corp., or Archemix, and Nektar Therapeutics, or Nektar, that impose significant milestone payment obligations on us in connection with our achievement of specific clinical, regulatory and commercial milestones with respect to Fovista. For example, in connection with the Novartis Agreement, we made a milestone payment of \$19.8 million to Nektar Therapeutics in June 2014.

#### Our expenses also will increase if and as we:

- · undertake additional clinical development of Fovista, if it is approved, in support of our efforts to broaden the label for Fovista;
- · conduct additional clinical trials of Zimura that may be required by regulatory authorities for us to seek marketing approval for Zimura for the treatment of geographic atrophy;
- · in-license or acquire the rights to other complementary products, product candidates or technologies for the treatment of ophthalmic diseases;
- · seek marketing approval for any product candidates that successfully complete clinical trials;
- · expand our outsourced manufacturing activities and establish sales, marketing, distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- · maintain, expand and protect our intellectual property portfolio;
- · hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

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As of June 30, 2014, we had cash, cash equivalents, and marketable securities of \$452.5 million, which includes the \$200.0 million upfront payment that we received upon the execution of the Novartis Agreement. We also had \$318.7 million in total liabilities as of June 30, 2014, including long-term liabilities of \$283.3 million relating to the Novo Agreement and deferred revenue associated with Novartis Agreement. In connection with the receipt of the upfront payment from Novartis, we made a milestone payment in June 2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million during the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations and capital expenditure requirements, as currently planned, through the end of 2017. Our capital requirements will also depend on other factors, including the success of our development and commercialization of our product candidates and whether we pursue the acquisition or in-licensing and subsequent development of additional product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our costs will increase if we experience delays in enrollment or if we increase our investigator fees for our clinical trials or expand the scope of our clinical trials and programs, including, for example by changing the geographic mix of sites at which patients are enrolled, or if we decide to increase other corporate or licensing activities or staffing.

Our current Phase 3 clinical program for Fovista is expected to continue through at least 2017, and substantial expenditures to complete the Phase 3 clinical program will be required after the receipt of initial, top-line data. Moreover, we are at the early stages of formulating our clinical development plan for Zimura, which we expect will continue for at least the next several years. At this time, we cannot reasonably estimate the remaining costs necessary to complete the clinical development of either Fovista or Zimura, complete process development and manufacturing scale-up activities associated with Fovista and Zimura and potentially seek marketing approval for Fovista and Zimura, or the nature, timing or costs of the efforts necessary to complete the development of Zimura and any other product candidate we may develop.

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

- the scope progress, costs and results of our Phase 3 clinical program for Fovista;
- the progress, costs and results of our planned clinical trials to further evaluate the potential benefit of Fovista in wet AMD when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need;
- the scope, progress, costs and results of our planned Phase 2/3 clinical trial evaluating Zimura for the treatment of geographic atrophy and whether and to what extent additional clinical trials may be required by regulatory authorities for us to seek marketing approval in this indication and our Phase 2 clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation;
- the costs and timing of process development and manufacturing scale-up activities associated with Fovista and Zimura;
- the costs, timing and outcome of regulatory review of Fovista and Zimura;
- the costs of commercialization activities for Fovista or Zimura if we receive, or expect to receive, marketing approval for either product candidate, including the costs and timing of expanding our outsourced manufacturing activities and establishing product sales, marketing and distribution capabilities;
- · subject to receipt of marketing approval, net revenue received from commercial sales of Fovista or Zimura, after milestone payments and royalties;
- the scope, progress, results and costs of clinical trials for any other product candidates that we may develop;

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- · our ability to establish collaborations on favorable terms, if at all;
- the extent to which we in-license or acquire rights to complimentary products, product candidates or technologies; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, as we can generate substantial product revenues, we may need to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. The potential future funding pursuant to the Novo Agreement is subject to enrollment of specified numbers of patients in our Phase 3 clinical trials of Fovista and our satisfying additional closing conditions and other obligations. Our potential enrollment milestone payments pursuant to the Novartis Agreement are also subject to enrollment of a specified number of patients in our Phase 3 clinical trials of Fovista. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of assets, including intellectual property rights, as collateral to secure our obligations under the Novo Agreement may limit our ability to obtain debt financing. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams 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 delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### Licensing and Commercialization Agreement with Novartis Pharma AG

On May 19, 2014, we entered into a Licensing and Commercialization Agreement with Novartis Pharma AG, which we refer to as the Novartis Agreement. Under the agreement with Novartis, we granted Novartis exclusive rights under specified patent rights, know-how and trademarks controlled by us to manufacture, from bulk active pharmaceutical ingredient supplied by us, standalone Fovista products and products combining Fovista with an anti-VEGF product to which Novartis has rights in a co-formulated product, for the treatment, prevention, cure or control of any human disease, disorder or condition of the eye, and to develop and commercialize those licensed products in all countries outside of the United States, which we refer to as the Novartis Territory. We have agreed to use commercially reasonable efforts to complete our ongoing pivotal Phase 3 clinical program for Fovista and Novartis has agreed to use commercially reasonable efforts to develop a standalone Fovista product and a co-formulated product containing Fovista and an anti-VEGF product to which Novartis has rights, as well as a pre-filled syringe presentation of such products and to use commercially reasonable efforts, subject to obtaining marketing approval, to commercialize licensed products in the Novartis Territory in accordance with agreed development and marketing plans. Novartis has also granted us options, subject to specified limitations, and to the extent such rights are controlled by Novartis, to obtain exclusive rights from Novartis to develop and commercialize in the United States the co-formulated and pre-filled syringe products developed by Novartis. We and Novartis have each granted the other options, subject to specified limitations, to obtain access to study data from certain clinical trials of licensed products that we or Novartis may conduct, including for use by the other in regulatory filings in its territory. We have agreed to exclusively supply Novartis, and Novartis has agreed to exclusively purchase from us, its clinical and commercial requirements for the bulk active pharmaceutical ingredient in Fovista for use in licensed products in the Novartis Territory. We have agreed not to commercialize any product comprising Fovista or any other anti-PDGF product in the ophthalmic field in the Novartis Territory.

Novartis paid us \$200.0 million upon execution of the Novartis Agreement. Novartis is also obligated to pay us up to an aggregate of \$130.0 million if we achieve specified patient enrollment milestones for its ongoing pivotal Phase 3 clinical program for Fovista, and up to an aggregate of an additional \$300.0 million upon achievement of specified approval milestones, including reimbursement approval in certain countries in the Novartis Territory. In addition, Novartis has agreed to pay us up to an aggregate of an additional \$400.0 million if Novartis achieves specified sales milestones in the Novartis Territory. Novartis also is obligated to pay us royalties with respect to standalone Fovista products and combination Fovista products that Novartis successfully commercializes. We will receive royalties at a mid-thirties percentage of net sales of standalone Fovista products and a royalty of approximately equal value for sales of combination Fovista products. Such royalties are subject to customary deductions, credits, and reductions for lack of patent coverage or market exclusivity. Novartis's obligation to pay such royalties will continue on a licensed product-by-licensed product and country-by-country basis until Novartis's last actual commercial sale of such licensed product in such country.

Novartis has agreed to pay our manufacturing costs plus a specified percentage margin for supplies of the bulk active pharmaceutical ingredient in Fovista that we supply to Novartis. If we or Novartis exercise our respective rights to obtain access to study data from clinical trials conducted by the other party, the party exercising the option will be obligated to pay the other party's associated past development costs and share with such other party any future associated development costs. If we exercise our option

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to obtain Novartis-controlled rights to develop, manufacture and commercialize any co-formulated Fovista product in the United States, we will be obligated to pay a specified percentage of Novartis's associated past development costs and share with Novartis any future associated development costs. We and Novartis will also need to negotiate and agree on financial and other terms that would apply to such rights. If we exercise our option to obtain Novartis-controlled rights to develop and commercialize a pre-filled syringe product in the United States, we will be obligated to either enter into a supply agreement with Novartis under which we will pay Novartis its manufacturing cost plus a specified percentage margin for supplies of Fovista products in pre-filled syringes that Novartis supplies to us, or obtain supplies of products in pre-filled syringes from a third party manufacturer and pay Novartis a low single-digit percentage of our net sales of such products.

We have retained control over the design and execution of our pivotal Phase 3 clinical program for Fovista and remain responsible for funding the costs of that program, subject to Novartis's responsibility to provide Lucentis, an anti-VEGF agent to which Novartis has rights in the Novartis Territory, for use in the Phase 3 trials in the Novartis Territory following the effective date of the Novartis agreement. Novartis will have control over, and will be responsible for the costs of, all other clinical trials that may be required to obtain marketing approvals in the Novartis Territory for licensed products under the agreement. Novartis is also responsible for costs associated with co-formulation development, pre-filled syringe development and other development costs in the Novartis Territory, but excluding regulatory filing fees in the European Union for the standalone Fovista product, for which we will be responsible.

The Novartis Agreement, unless earlier terminated by us or Novartis, will expire upon the expiration of Novartis's obligation to pay us royalties on net sales of licensed products. We and Novartis each may terminate the agreement if the other party materially breaches the agreement and does not cure such breach within a specified cure period, if the other party experiences any specified insolvency event, if the other party challenges or assists a third party in challenging the validity or enforceability of certain patent rights controlled by the terminating party, or if the parties are prevented in any manner that materially adversely affects the progression of the development or commercialization of licensed products for a specified period as a result of specified governmental actions. Novartis may terminate the agreement at any time without cause, or within a specified period after a change in control of us, as defined in the agreement, or for specified safety reasons, effective at the end of a specified period following Novartis's written notice to us of Novartis's election to terminate the agreement. We may also terminate the agreement if Novartis determines to seek marketing approval of an alternative anti-PDGF product in the Novartis Territory as more fully described below. If we elect to terminate the agreement because specified governmental actions prevent the parties from materially progressing the development or commercialization of licensed products as described above, we will be required to pay a substantial termination fee, with the specific amount of such fee determined based on the effective date of the termination. Following any termination, all rights to Fovista that we granted to Novartis, including, without limitation, the right to commercialize standalone Fovista products in the Novartis Territory, will revert to us, Novartis will perform specified activities in connection with transitioning to us the rights and responsibilities for the continued development, manufacture and commercializatio

Novartis has agreed to specified limitations on its ability to in-license, acquire or commercialize any anti-PDGF product that does not contain Fovista, which we refer to as an Alternative Anti-PDGF Product in the Novartis Territory and, to the extent Novartis develops, in-licenses or acquires such a

product, to make such product available to us in the United States under specified option conditions. If we exercise our option, we will be obligated to make certain payments to Novartis, including specified milestone and royalty payments. The amounts of such payments will vary based on the product's stage of clinical development at the time we exercise our option, whether the product is a standalone or combination product and whether Novartis exercises an option to co-promote such product in the United States. If Novartis determines to seek marketing approval of an Alternative Anti-PDGF Product in the Novartis Territory, we will, subject to specified limitations, have the option to terminate the agreement, convert Novartis's exclusive licenses into non-exclusive licenses, or elect to receive a royalty on sales of such product by Novartis. If we elect to terminate the agreement, Novartis will, subject to specified limitations, be required to pay to us, certain payments based on achievement, with respect to such product, of the milestones that would have otherwise applied to licensed products under the agreement.

The agreement contains standstill provisions pursuant to which Novartis agrees to certain restrictions relating to our voting securities until marketing approval for a standalone Fovista product is granted in either the United States or the European Union. The agreement contains indemnification and dispute resolution provisions that are customary for agreements of its kind.

#### Clinical Manufacturing and Supply Agreement with Agilent Technologies, Inc.

On May 2, 2014, we entered into a Clinical Manufacturing and Supply Agreement with Agilent Technologies, Inc. pursuant to which Agilent has agreed to manufacture and supply to us, and we have agreed to purchase from Agilent, a specified percentage of our clinical requirements in specified jurisdictions of the active pharmaceutical ingredient in Fovista. The agreement has an initial five

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year term, which is subject to automatic renewal absent termination by either party in accordance with the terms of the agreement. The agreement provides for pricing structured on a tiered basis with the price reduced as the volume ordered increases. We may terminate the agreement or any statement of work thereunder upon 12 months prior written notice to Agilent and Agilent may terminate the agreement if we do not, over a specified period, purchase and take delivery from Agilent of a specified minimum quantity of active pharmaceutical ingredient for Fovista. Each party also has the right to terminate the agreement for other customary reasons such as material breach and bankruptcy. The agreement contains provisions relating to compliance by Agilent with current Good Manufacturing Practices, cooperation by Agilent in connection with marketing applications for Fovista, indemnification, confidentiality, dispute resolution and other customary matters for an agreement of this kind.

#### Royalty Financing Agreement with Novo A/S

In May 2013, we entered into the Novo Agreement, pursuant to which we may obtain royalty financing in three tranches in an amount of up to \$125.0 million in return for the sale to Novo A/S of aggregate royalties at low to mid-single-digit percentages of worldwide sales of Fovista, with the royalty percentage determined by the amount of funding provided by Novo A/S. The first and second tranches of the royalty financing, in which Novo A/S purchased two low single-digit royalty interests and paid us \$83.3 million in the aggregate, closed in May 2013 and January 2014. Under the Novo agreement, Novo A/S agreed to purchase from us, and we have the option to sell to Novo A/S, an additional low single-digit royalty interest on worldwide sales of Fovista, for a purchase price of \$41.7 million. If the final royalty interest under the Novo Agreement is purchased, Novo A/S will have a right to receive royalties on worldwide sales of Fovista at a mid-single-digit percentage. The closing of the final financing tranche is subject to the enrollment of a specified number of patients in our Phase 3 clinical trials of Fovista and our satisfying additional closing conditions and other obligations.

Under specified circumstances, including terminations, suspensions or delays of our Phase 3 clinical trials for Fovista, the failure of certain closing conditions to be satisfied or transactions involving a change of control of us in which the acquiring party does not meet certain specifications, Novo A/S has the option to cancel the subsequent purchase and sale of the final royalty interest. We also have the option to cancel the subsequent purchase and sale of the final royalty interest in specified circumstances, including terminations, suspensions or delays in our Phase 3 clinical trials for Fovista, any change of control of us or the completion of equity financings meeting specified thresholds.

The royalty payment period begins on the commercial launch of Fovista and ends, on a country-by-country basis, on the latest to occur of the twelfth anniversary of the commercial launch of Fovista, the expiration of certain patent rights covering Fovista, and the expiration of regulatory exclusivity for Fovista, in each applicable country. Royalty payments will be payable quarterly in arrears during the royalty period. Our obligations under the Novo Agreement may also apply to certain other anti-platelet derived growth factor, or anti-PDGF, products we may develop.

We used a portion of the proceeds that we initially received under the Novo Agreement to repay in full an aggregate of \$14.4 million of outstanding principal, interest and fees under our venture debt facility. The Novo Agreement provides that we will use the remaining proceeds we received, and future proceeds, if any, from the sale of royalty interests under the Novo Agreement, primarily to support clinical development and regulatory activities for Fovista and, to the extent applicable, other specified products we may develop pursuant to the terms of the Novo Agreement, and for general corporate expenses. We intend to use the proceeds from the second tranche of financing that we received in January 2014 to support clinical development and regulatory activities for Fovista.

The Novo Agreement requires the establishment by us and Novo A/S of a joint oversight committee in relation to the development of Fovista in the event that Novo A/S does not continue to have a representative on our board of directors. The Novo Agreement also contains customary representations and warranties, as well as certain covenants relating to the operation of our business, including covenants requiring us to use commercially reasonable efforts to continue our development of Fovista, to file, prosecute and maintain certain patent rights and, in our reasonable judgment, to pursue claims of infringement of our intellectual property rights. The Novo Agreement also places certain restrictions on our business, including restrictions on our ability to grant security interests in our intellectual property to third parties, to sell, transfer or out-license intellectual property, or to grant others rights to receive royalties on sales of Fovista and certain other products. We reimbursed Novo A/S for specified legal and other expenses and are required to provide Novo A/S with certain continuing information rights. We have agreed to indemnify Novo A/S and its representatives with respect to certain matters, including with respect to any third-party infringement or product liability claims relating to our products. Our obligations under the Novo agreement are secured by a lien on certain of our intellectual property and other rights related to Fovista and other anti-PDGF products we may develop.

#### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of June 30, 2014:

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	Payments Due by Period									
	Total		Less than 1 year		1-3 years		3-5 years		More than 5 years	
	(\$ in thousands)									
Operating Leases (1)	\$ 4,714	\$	890	\$	1,760	\$	1,654	\$	410	
Purchase Obligations (2)	\$ 3,210	\$	3,210	\$	_	\$	_	\$	_	
Total (3)	\$ 7,924	\$	4,100	\$	1,760	\$	1,654	\$	410	

- (1) Operating lease obligations reflect our obligation to make payments in connection with leases for our office space.
- (2) Purchase obligations represent our commitments under certain of our supply agreements.
  - 3) This table does not include (a) any milestone payments which may become payable to third parties under license agreements as the timing and likelihood of such payments are not known with certainty, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above and (d) the royalty purchase liability of \$83.3 million due to the fact that the royalty payment period is not known.

Under various agreements, we may be required to pay royalties and make milestone payments. These agreements include the following:

- · Under our acquisition agreement with OSI (Eyetech), Inc., which agreement is now held by OSI Pharmaceuticals, LLC., or OSI Pharmaceuticals, a subsidiary of Astellas US, LLC, for rights to particular anti-PDGF aptamers, including Fovista, we are obligated to pay to OSI Pharmaceuticals future one-time payments of \$12.0 million in the aggregate upon marketing approval in the United States and the European Union of a covered anti-PDGF product. We also are obligated to pay to OSI Pharmaceuticals a royalty at a low single-digit percentage of net sales of any covered anti-PDGF product we successfully commercialize.
- Under a license agreement with Archemix Corp., or Archemix, with respect to pharmaceutical products comprised of or derived from any anti-PDGF aptamer, we are obligated to make future payments to Archemix of up to an aggregate of \$14.0 million if we achieve specified clinical and regulatory milestones with respect to Fovista, up to an aggregate of \$3.0 million if we achieve specified commercial milestones with respect to Fovista and, for each other anti-PDGF aptamer product that we may develop under the agreement, up to an aggregate of approximately \$18.8 million if we achieve specified clinical and regulatory milestones and up to an aggregate of \$3.0 million if we achieve specified commercial milestones. No royalties are payable to Archemix under this license agreement.
- · Under a license agreement with Archemix with respect to pharmaceutical products comprised of or derived from anti-C5 aptamers, for each anti-C5 aptamer product that we may develop under the agreement, including Zimura, we are obligated to make future payments to Archemix of up to an aggregate of \$57.5 million if we achieve specified development, clinical and regulatory milestones and, as to all anti-C5 products under the agreement collectively, up to an aggregate of \$22.5 million if we achieve specified commercial milestones. We are also obligated to pay Archemix a double-digit percentage of specified non-royalty payments we may receive from any sublicensee of our rights under this license agreement. No royalties are payable to Archemix under this license agreement.
- · Under a license, manufacturing and supply agreement with Nektar Therapeutics, or Nektar, for specified pegylation reagents used to manufacture Fovista, we are obligated to make future payments to Nektar of up to an aggregate of \$6.5 million if we achieve specified clinical and regulatory milestones, and an additional payment of \$3.0 million if we achieve a specified commercial milestone with respect to Fovista. We are obligated to pay Nektar tiered royalties at low to mid-single-digit percentages of net sales of any licensed product we successfully commercialize, with the royalty percentage determined by our level of licensed product sales and the extent of patent coverage for the licensed product and whether we have granted a third-party commercialization rights to the licensed product. In June 2014, we paid Nektar \$19.8 million in connection with our entry into the Novartis Agreement. Our agreement with Nektar also provides that we pay double-digit percentage of other specified amounts, such as milestone payments, we receive in connection with any such commercialization agreement, including the Novartis Agreement, subject to agreed minimum and maximum amounts.
- · Under the Novo Agreement, with respect to Fovista, we are obligated to pay Novo A/S a low to mid-single-digit percentage royalty based on worldwide sales of Fovista, with the royalty percentage determined by the amount of funding provided by Novo A/S. See "—Royalty Financing" above for further information about Novo Agreement.

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· Under the clinical supply agreement with Agilent Technologies, Inc., Agilent has agreed to manufacture and supply to us, and we have agreed to purchase from Agilent, a specified percentage of our clinical requirements in specified jurisdictions of the active pharmaceutical ingredient in our product candidate Fovista. Our agreement with Agilent has an initial five year term, which is subject to automatic renewal absent termination by either party in accordance with the terms of the Agreement. The Agreement provides for pricing structured on a tiered basis with the price reduced as the volume ordered increases. We terminate the agreement or any statement of work thereunder upon 12 months prior written notice to Agilent.

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur.

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 represent a significant cost in clinical development. We can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission rules.

#### 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 marketable securities of \$452.5 million as of June 30, 2014, consisting of cash, money market funds that invest in U.S. Treasury securities, and direct investment in U.S. Treasury 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. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. 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 CROs and contract manufacturers globally. 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 June 30, 2014, 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 June 30, 2014. 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 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 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 June 30, 2014, 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.

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#### **Changes in Internal Control over Financial Reporting**

No change 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 three months ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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#### PART II—OTHER INFORMATION

#### Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

#### 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 ones 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 Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Since inception, we have experienced significant cash outflows in funding our operations. Our net loss was \$73.2 million for the six months ended June 30, 2014 and \$14.6 million for the six months ended June 30, 2013. As of June 30, 2014, we had a deficit accumulated of \$256.2 million. To date, we have not generated any revenues from product sales and have financed our operations primarily through private placements of our preferred stock, venture debt borrowings, funds received under the Novo Agreement, our initial public offering, which we closed in September 2013, our follow-on public offering, which we closed in February 2014 and funds we received under the Novartis Agreement, which we entered into in May 2014. We received net proceeds from our initial public offering of \$175.6 million, after deducting underwriting discounts and other offering expenses payable by us. We received net proceeds from our follow-on public offering of \$55.4 million, after deducting underwriting discounts and commissions and other offering expenses

payable by us. In May 2014, we received \$200.0 million from Novartis, which constituted the upfront payment under the Novartis Agreement. In connection with the receipt of the payment from Novartis, we a made milestone payment in June 2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million during the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

We have devoted substantially all of our financial resources and efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

Our product candidates, Fovista and Zimura, are still in clinical development. We expect our expenses to increase substantially, particularly as we continue the development of Fovista in our Phase 3 clinical program for the treatment of wet AMD. We initiated our pivotal Phase 3 clinical program for Fovista in August 2013. We plan to enroll a total of 1,866 patients for this program, most of which we expect to enroll in 2014 and 2015. In addition, we also expect our expenses to increase as we further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need, pursue the development of Zimura, with an initial focus on the treatment of geographic atrophy, a severe form of dry AMD, and pursue a planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation. We expect these expenses to increase as patient enrollment increases. In addition, if we obtain marketing approval for Fovista, Zimura or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We are party to agreements, specifically an asset acquisition agreement with OSI (Eyetech), Inc., which agreement is now held by OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC, and license agreements with Archemix Corp., and Nektar Therapeutics, that impose significant milestone payment obligations on us in connection with our achievement of specific clinical, regulatory and commercial milestones with respect to Fovista. See "Business—Acquisition and License Agreements" for more information. Furthermore, we expect to incur additional costs associated with being a public company, including legal, compliance, accounting and investor and public relations expenses, as well as increase

Our expenses also will increase if and as we:

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- · undertake additional clinical development of Fovista, if it is approved, in support of our efforts to broaden the label for Fovista;
- · conduct additional clinical trials of Zimura that may be required for us to seek marketing approval of Zimura for the treatment of geographic atrophy;
- · in-license or acquire the rights to other complementary products, product candidates or technologies for the treatment of ophthalmic diseases;
- · seek marketing approval for any product candidates that successfully complete clinical trials;
- · expand our outsourced manufacturing activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any of our product candidates;
- · maintain, expand and protect our intellectual property portfolio;
- · hire additional clinical, quality control and scientific personnel; and
- · add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts.

If we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or regulatory authorities in other jurisdictions to perform clinical or nonclinical trials or other studies in addition to those we currently expect to conduct, or if there are any delays in completing the clinical trials of Fovista or Zimura, or the development of any of other product candidates that we may develop, our expenses could increase. Our costs will also increase if we increase our investigator fees for our clinical trials or expand the scope of our clinical trials and programs, including, for example, by changing the geographic mix of sites at which patients are enrolled, or to increase other corporate or licensing activities or staffing.

Our ability to become and remain profitable depends on our ability to generate revenue in excess of our expenses. We do not expect to generate and maintain significant revenue from product sales unless, and until, we obtain marketing approval for, and commercialize, Fovista, Zimura or other product candidates that we may develop. Our capital requirements will depend on many factors, including the success of our development and commercialization of our product candidates and whether we pursue the acquisition or in-licensing and subsequent development of 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. Our ability to commercialize our product candidates, in particular Fovista, will require us to be successful in a range of challenging activities, including:

- · obtaining favorable results from our Phase 3 clinical program for Fovista;
- if initiated, obtaining favorable results, especially with respect to safety, in our other planned clinical trials involving Fovista;
- · subject to obtaining favorable results from our Phase 3 clinical program, applying for and obtaining marketing approval for Fovista;
- establishing sales, marketing and distribution capabilities to effectively market and sell Fovista in the United States with our own specialty sales force targeting retinal specialists;
- · successfully maintaining our arrangement with Novartis to commercialize Fovista in markets outside the United States;
- · obtaining adequate coverage and reimbursement for our product candidates, if approved, from governmental and third-party payors;

- · protecting our rights to our intellectual property portfolio related to Fovista; and
- ensuring the manufacture of commercial quantities of Fovista.

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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 profitability. In addition, our profitability will depend, in part, on our commercialization partners' including Novartis's, ability to effectively market and sell Fovista, Zimura or other product candidates we may develop, if approved outside the United States and to obtain adequate coverage and reimbursement of such product candidates from governmental and third party payors. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain 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 decline in the value of our company could also cause our stockholders to lose all or part of their investment.

#### We have broad discretion in the use of our available cash and other sources of funding and we may not use them effectively.

Our management has broad discretion in the use of our available cash and other sources of funding and could spend those resources in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our available cash in a manner that does not produce adequate income, if any, or that loses value.

#### Our short operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We were incorporated and commenced active operations in 2007. Our operations to date have been limited to organizing and staffing our company, acquiring rights to product candidates, business planning, raising capital and developing Fovista, Zimura and other product candidates. We have not yet demonstrated our ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a product development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

## We may need additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase substantially, particularly as we continue the development of Fovista in our Phase 3 clinical program for the treatment of wet AMD. We plan to enroll a total of 1,866 patients for this program, most of which we expect to enroll in 2014 and 2015. In addition, we also expect our expenses to increase as we further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need, pursue the development of Zimura, with an initial focus on the treatment of geographic atrophy, a severe form of dry AMD, and pursue an additional planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation. In addition, if we obtain marketing approval for Fovista, Zimura or any other product candidate that we develop, we expect to incur significant commercialization expenses in the United States with regard to Fovista and worldwide with regards to other product candidates, related to product sales, marketing, distribution and manufacturing. Our expenses will increase if we suffer any delays in our Phase 3 clinical program for Fovista, including delays in receipt of regulatory clearance to begin our Phase 3 clinical trials in jurisdictions where clearance is required but not yet obtained, or delays in enrollment of patients. Furthermore, we expect to incur additional costs associated with being a public company, hiring additional personnel and expanding our facilities. Accordingly, we may need to obtain additional funding in connection with our continuing operations prior to attaining profitability. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of June 30, 2014, we had cash, cash equivalents, and marketable securities of \$452.5 million, which includes the \$200.0 million upfront payment that we received upon the execution of the Novartis Agreement. We also had \$318.7 million in total liabilities as of June 30, 2014, including long-term liabilities of \$283.3 million relating to the Novo Agreement and deferred revenue associated with the Novartis Agreement. In connection with the receipt of the payment from Novartis, we made a milestone payment in June 2014 of approximately \$19.8 million under one of our agreements. We currently estimate that we will make income tax payments of approximately \$29.5 million in the second half of 2014 relating to taxable income that resulted from the receipt of the \$200.0 million upfront payment from Novartis and \$41.7 million in proceeds from the Novo Agreement.

We believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations and capital expenditure requirements, as currently planned, through the end of 2017. We expect to obtain initial, top-line data from our

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Phase 3 clinical program for Fovista in 2016. Our capital requirements will also depend on other factors, including the success of our development and commercialization of our product candidates and whether we pursue the acquisition or in-licensing and subsequent development of additional product candidates.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We are planning to spend significant additional funds on our Phase 3 clinical program for Fovista, on our other planned clinical programs, including additional clinical trials to further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need, an additional planned clinical trial evaluating Zimura for the treatment of geographic atrophy,

pursue planned clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation, and for general corporate purposes and working capital. Costs related to our clinical programs could exceed our expectations if we experience delays in our clinical trials, including because of the timing of our patient enrollment, the availability of drug supply for our clinical trials or for other reasons. Our costs will also increase if we increase investigator fees for our clinical trials or expand the scope of our clinical trials and programs, including, for example, by changing the geographic mix of sites at which patients are enrolled, or to increase other corporate or licensing activities or staffing.

Our current Phase 3 clinical program for Fovista is expected to continue through at least 2017, and substantial expenditures to complete the Phase 3 clinical program will be required after the receipt of initial, top-line data. Moreover, we are at the early stages of formulating our clinical development plan for Zimura. We expect the clinical development of Zimura will continue for at least the next several years. At this time, we cannot reasonably estimate the remaining costs necessary to complete the clinical development of either Fovista or Zimura, complete process development and manufacturing scale-up activities associated with Fovista and Zimura and potentially seek marketing approval for Fovista or Zimura, or the nature, timing or costs of the efforts necessary to complete the development of any other product candidate we may develop.

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

- the scope, progress, costs and results of our Phase 3 clinical program for Fovista;
- the progress, costs and results of our planned additional clinical trials to further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet need;
- the scope, progress, results and costs of our planned Phase 2/3 clinical trial evaluating Zimura for the treatment of geographic atrophy and whether and to what extent additional clinical trials may be required by regulatory authorities for us to seek marketing approval in this indication and our Phase 2 clinical trial evaluating Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are believed to have complement mediated inflammation;
- the costs and timing of process development and manufacturing scale-up activities associated with Fovista and Zimura;
- the costs, timing and outcome of regulatory review of Fovista and Zimura;
- the costs of commercialization activities for Fovista or Zimura if we receive, or expect to receive, marketing approval for either product candidate, including the costs and timing of expanding our outsourced manufacturing activities and establishing product sales, marketing and distribution capabilities;
- · subject to receipt of marketing approval, revenue received from commercial sales of Fovista or Zimura, after milestone payments and royalties;
- the scope, progress, results and costs of our clinical trials for any other product candidates that we may acquire or in-license and subsequently develop;
- · our ability to establish additional collaborations on favorable terms, if at all;
- $\cdot$  the extent to which we in-license or acquire rights to complementary products, product candidates or technologies; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims.

Our commercial revenues, if any, will be derived from sales of Fovista, Zimura or any other products that we successfully develop, none of which we expect to be commercially available for several years, if at all. In addition, if approved, Fovista or Zimura

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or any product that we acquire or in-license may not achieve commercial success. If that is the case, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. 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.

If we fail to enroll patients in our Phase 3 clinical trials of Fovista as planned or fail to comply with our obligations in the Novo Agreement or the Novartis Agreement, we could lose access to funds that are important to our business, which may force us to delay or terminate the development of Fovista. In addition, a default under the Novo Agreement would permit Novo A/S to foreclose on the Fovista intellectual property.

In May 2014, we entered into the Novartis Agreement. Among other payments, Novartis is obligated under the agreement to pay us up to an aggregate of \$130.0 million if we achieve specified patient enrollment milestones for our ongoing pivotal Phase 3 clinical program for Fovista. In May 2013, we entered into a royalty purchase and sale agreement with Novo A/S, which we refer to as the Novo Agreement, for a financing of up to \$125.0 million in return for the sale to Novo A/S of royalty interests in worldwide sales of Fovista. We received approximately \$83.3 million of this royalty financing in two separate tranches in May 2013 and January 2014. We are obligated to pay Novo A/S royalties in the low to mid-single-digit percentages of worldwide sales of Fovista, with the royalty percentage determined by the amount of funding provided by Novo A/S.

We are subject to diligence and other obligations under the Novo Agreement and the Novartis Agreement. If we fail to enroll the specified numbers of patients in our Phase 3 clinical trials of Fovista and satisfy additional closing conditions under the Novo Agreement or fail to satisfy our other obligations, Novo A/S will have no further obligation to pay additional funds to us under the Novo Agreement and we may fail to trigger the enrollment-based milestone payments under the Novartis Agreement. This could limit our ability to continue the development programs for our product candidates. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay or terminate our research and development programs, including for Fovista, or any future commercialization efforts.

In addition, our obligations under the Novo Agreement are secured by collateral, which includes certain intellectual property rights, including all of our intellectual property rights relating to Fovista and regulatory approvals, if any, of Fovista. If we fail to satisfy our diligence obligations or breach any other of our obligations under the Novo Agreement and fail to cure the breach within any applicable grace period, Novo A/S could declare an event of default. In such event, Novo A/S could seek to foreclose on the collateral securing our obligations. If Novo A/S successfully does so, we would lose our rights to develop and commercialize Fovista.

Our obligations under the Novo Agreement and the pledge of our intellectual property rights in and regulatory approvals, if any, of Fovista as collateral under such agreement may limit our ability to obtain debt financing.

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, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, potential milestone payments under collaborations, strategic alliances and marketing, distribution or licensing arrangements. The potential funding pursuant to the Novo Agreement is subject to enrollment of specified numbers of patients in our Phase 3 clinical trials of Fovista and our satisfying additional closing conditions and other obligations. The potential milestone payments under the Novartis Agreement are subject to our achievement of specified clinical, regulatory and commercial events related to Fovista. We do not have any other committed external source of funds besides these two sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of assets, including intellectual property rights, as collateral to secure our obligations under the Novo Agreement may limit our ability to obtain debt financing.

If we raise additional funds through collaborations, 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 delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

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#### **Risks Related to Product Development and Commercialization**

We depend heavily on the success of our lead product candidate, Fovista, which we are developing to be administered in combination with anti-VEGF drugs for the treatment of patients with wet AMD. In addition, we also depend on the success of Zimura, which we are developing with an initial focus on the treatment of geographic atrophy, a severe form of dry AMD. If we are unable to complete the clinical development of either of these product candidates, if we are unable to obtain marketing approvals for either of these product candidates, or if either of these product candidates is approved and we or our commercialization partner for Fovista outside the United States, Novartis, fail to successfully commercialize the product candidate or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of Fovista to be administered in combination with anti-VEGF drugs for the treatment of patients with wet AMD. There remains a significant risk that we will fail to successfully develop Fovista. The results of our Phase 2b clinical trial may not be predictive of the results of our Phase 3 clinical program due, in part, to the fact that we have no clinical data on Fovista combination therapy in any clinical trial longer than 24 weeks, that we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial, that we have no clinical data on the effects of Fovista when administered in combination with Avastin or Eylea and that we plan to conduct our Phase 3 clinical trials at many clinical centers that were not included in our Phase 2b clinical trial.

We do not expect to have initial, top-line data from our Phase 3 clinical program for Fovista available until 2016. The timing of the availability of such top-line data and the completion of our Phase 3 clinical program is dependent, in part, on our ability to locate and enroll a sufficient number of eligible patients in our Phase 3 clinical program on a timely basis. The timing of the availability of initial, top-line data from our Phase 3 clinical trial evaluating the safety and efficacy of Fovista administered in combination with each of Avastin or Eylea may be subject to particular variability because, prior to the initiation of our Phase 3 clinical program, we had no clinical experience testing Fovista administered in combination with Avastin or Eylea. Avastin is not approved for intravitreal use in treating wet AMD, and regulatory authorities in certain countries may not allow, or physicians and patients may choose not to participate in, a clinical trial in which Avastin is administered in combination with Fovista for the treatment of wet AMD. Even if we ultimately obtain statistically significant, positive results from our Phase 3 clinical program, we do not expect to submit applications for marketing approval for Fovista until the end of 2016.

If we are not able to obtain data from our Phase 3 clinical trial evaluating Fovista administered in combination with each of Avastin or Eylea when data from our other two Phase 3 clinical trials evaluating Fovista administered in combination with Lucentis are available, we may nonetheless decide to proceed with submitting applications for marketing approval for Fovista only in combination with Lucentis, we may determine either to delay seeking approval of Fovista in combination with Avastin or Eylea until after regulatory authorities have considered and acted on our applications for Fovista in combination with Lucentis, or to amend our applications once data from our third Phase 3 clinical trial become available. If we were to delay seeking approval of Fovista in combination with Avastin or Eylea pending regulatory action on our applications for Fovista in combination with Lucentis, the FDA or other regulatory authorities could defer taking action on our applications while data remain outstanding from our third Phase 3 clinical trial. Moreover, if we subsequently amend our applications for marketing approval when data from our third Phase 3 clinical trial become available, we may experience further delays in our application process.

Additionally, we expect that our Phase 3 clinical trials will continue in accordance with their protocols after we submit applications for marketing approval, and the conclusions of those trials may yield data that are inconsistent with the initial data used to support our applications. Furthermore, we expect to commence additional clinical trials to further evaluate the potential benefit of Fovista in wet AMD, when administered in combination with anti-VEGF drugs, and in other ophthalmic diseases and conditions with unmet medical need during the course of our ongoing Phase 3 clinical development program, and to evaluate Zimura and Fovista administered in combination with an anti-VEGF drug for the treatment of anti-VEGF resistant wet AMD patients who are

believed to have complement mediated inflammation. We are also supplying Fovista for third-party sponsored clinical trials. Adverse safety events or negative or inconclusive efficacy results in any of these trials may impact the progress of our Phase 3 clinical program. In addition, adverse results from any of these additional planned clinical trials would be disclosed in and could negatively impact our applications for marketing approval for Fovista administered in combination with anti-VEGF drugs for the treatment of wet AMD. As a result of these and other factors, we cannot accurately predict when or if Fovista will prove effective or safe in humans or will receive marketing approval.

In addition, we have invested substantial financial resources in the development of Zimura for the treatment of patients with both dry and wet AMD. There remains a significant risk that we will fail to successfully develop Zimura. We have very limited data from our completed Phase 2a clinical trial evaluating the safety and effectiveness of Zimura for the treatment of dry AMD and our completed Phase 2a clinical trial evaluating the safety and effectiveness of Zimura administered in combination with Lucentis for the treatment of wet AMD. These trials enrolled 47 patients and 60 patients, respectively, and neither trial included a control arm. Furthermore, we have no preclinical or clinical data on the effects of Zimura when administered in combination with both Fovista and an anti-VEGF drug.

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We do not expect to receive interim results from our planned Phase 2/3 clinical trial of Zimura for the treatment of dry AMD until 2016. Furthermore, we do not expect to receive initial results from our planned Phase 2 clinical trial of Zimura and Fovista administered in combination with an anti-VEGF drug until 2016. The timing of the completion of and the availability of initial results from these planned clinical trials is dependent, in part, on our ability to complete manufacturing scale-up activities for Zimura and to locate and enroll a sufficient number of eligible patients in our planned trials on a timely basis. The timing of the receipt of initial results from our Phase 2 clinical trial evaluating the safety and efficacy of Zimura and Fovista administered in combination with an anti-VEGF drug may be subject to particular variability because we have no clinical experience testing Zimura administered in combination with Fovista and an anti-VEGF drug.

Although our current development plan for Zimura calls for us to initiate a Phase 2/3 clinical trial evaluating the safety and efficacy of Zimura in treating patients with geographic atrophy, we may not initiate or complete this clinical trial for Zimura or any other clinical trial for Fovista, Zimura or any other product candidates that we may develop in accordance with our plans.

Although our plans for additional clinical trials reflect our current expectations regarding the endpoints, duration and number of patients to be included in these trials, we have only had preliminary discussions with regulatory authorities regarding our trial designs. As we continue these discussions, our plans may change significantly based on feedback from such regulatory authorities.

Our ability to generate revenues from product sales, which we do not expect will occur before 2017, if ever, will depend heavily on our obtaining marketing approval for and commercializing our product candidates, and in particular, Fovista and Zimura. The success of these product candidates will depend on several factors, including the following:

- · obtaining favorable results from clinical trials;
- · making arrangements with third-party manufacturers and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- for Fovista, receipt of marketing approvals from applicable regulatory authorities for the use of Fovista in combination with anti-VEGF drugs for the treatment of wet AMD, and in particular, which anti-VEGF drugs are included in any such approval given that Avastin, one of the current standard of care anti-VEGF drugs, is not approved for intravitreal use;
- · for Zimura, receipt of marketing approvals from applicable regulatory authorities for the use of Zimura for the treatment of dry AMD or the use of Zimura administered in combination with Fovista and anti-VEGF drugs for the treatment of wet AMD;
- the scope of the label that may be approved by applicable regulatory authorities, including the specific indication for which the product may be approved;
- · launching commercial sales of the product candidate, if and when approved, whether alone or in collaboration with others, including Novartis for Fovista:
- · acceptance of the product candidate, if and when approved, by patients, the medical community and third-party payors;
- · for Fovista, continued, widespread use of anti-VEGF therapies in the treatment of wet AMD in combination with which Fovista will be used;
- 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 following approval:
- · obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- · protecting our rights in our intellectual property portfolio.

Successful development of Fovista for the further treatment of wet AMD, the treatment of additional ophthalmic conditions, if any, or for use in other patient populations and our ability, if it is approved, to broaden the label for Fovista will depend on similar factors.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize Fovista, Zimura or any other product candidates that we may develop, which would materially harm our business.

If clinical trials of Fovista, Zimura or any other product candidate that we may develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of Fovista, Zimura or any other product candidate.

Before obtaining approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. 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. Moreover, 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.

Our Phase 2b clinical trial evaluated a combination of Fovista and Lucentis. In this trial, patients treated with a combination of 0.3 mg of Fovista and Lucentis did not achieve statistically significant superiority compared to Lucentis monotherapy based on the pre-specified primary endpoint of mean change in visual acuity from baseline at the 24 week time point. Although a combination of 1.5 mg of Fovista and Lucentis demonstrated statistically significant superiority in this trial compared to Lucentis monotherapy based on the pre-specified primary endpoint of mean change in visual acuity from baseline at the 24 week time point, we may nonetheless fail to achieve success in our Phase 3 clinical trials involving a combination of 1.5 mg of Fovista and Lucentis for a variety of potential reasons.

- The primary endpoint of mean change in visual acuity in our Phase 2b clinical trial was measured 24 weeks after the first dose of Fovista. The primary endpoint of mean change in visual acuity in our Phase 3 clinical program will be measured 12 months after the first dose of Fovista. We have no clinical data on Fovista combination therapy in any clinical trial longer than 24 weeks. We have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial. If the positive results we observed at 24 weeks in our Phase 2b clinical trial are not observed at 12 months, we likely will not receive marketing approval for Fovista.
- Retrospective subgroup analyses that we performed on the results of our Phase 2b clinical trial may not be predictive of the results of our Phase 3 clinical program. Furthermore, our retrospective analysis of retinal images of subretinal fibrosis from our Phase 2b clinical trial, to date, is based only on our initial assessment of a group of patients who experienced poor visual outcome following treatment with either 1.5 mg of Fovista in combination with 0.5 mg of Lucentis or Lucentis monotherapy in the trial. To date, our analysis is consistent with that of the masked independent reader, although the analysis is ongoing. While we believe that our retrospective analyses further support the results from our primary endpoint and our proposed mechanism of action, retrospective analyses performed after unblinding trial results can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses. Our proposed mechanism of action, in particular, as it relates to the inhibition of subretinal fibrosis, although scientifically rational, may not be supported by our confirmatory analysis of our Phase 2b retinal images or by future clinical trials. Our belief regarding Fovista's potential, when administered in combination with an anti-VEGF drug, to inhibit subretinal fibrosis and retinal scarring, may change based on such confirmatory analysis, subsequent clinical trials or other factors.
- · We are conducting our Phase 3 clinical trials at many clinical centers that were not included in our Phase 2b clinical trial. The introduction of new centers, and the resulting involvement of new treating physicians, can introduce additional variability into the conduct of the trials in accordance with their protocols and may result in greater variability of patient outcomes, which could adversely affect our ability to detect statistically significant differences between patients treated with 1.5 mg of Fovista administered in combination with an anti-VEGF drug and anti-VEGF drug monotherapy.

Furthermore, our Phase 3 clinical program involves two Phase 3 clinical trials testing a combination of 1.5 mg of Fovista and Lucentis for the treatment of wet AMD and one trial testing a combination of 1.5 mg of Fovista with each of Avastin or Eylea for the treatment of wet AMD. We have no clinical efficacy data on the effects of Fovista when administered in combination with Avastin or Eylea for the treatment of patients with wet AMD. Avastin is not approved for such use.

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Fovista administered in combination with Lucentis was generally well tolerated in our Phase 1 and Phase 2b clinical trials. However, the results of these clinical trials may not be predictive of the results of our Phase 3 clinical program for Fovista due, in part, to the fact that we have no clinical safety data on patient exposure to Fovista administered in combination with any anti-VEGF drug for longer than 24 weeks and that we have no clinical safety data on the effects of Fovista when administered in combination with Avastin or Eylea.

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. If a combination of 1.5 mg of Fovista and Lucentis fails to achieve superiority over Lucentis monotherapy with statistical significance on the primary endpoint of mean change in visual acuity from baseline at 12 months in both of our Phase 3 clinical trials evaluating the safety and efficacy of this combination, we likely will not receive marketing approval for Fovista even if the combination of 1.5 mg of Fovista with Avastin or Eylea achieves superiority over Avastin or Eylea monotherapy with statistical significance on the primary endpoint in one of our Phase 3 clinical trials. There are a variety of other possible outcomes of our Phase 3 clinical trials. As described below, positive outcomes in one or more of our Phase 3 clinical trials may not be sufficient for the FDA or similar regulatory authorities outside the United States to grant marketing approval for Fovista.

· If a combination of 1.5 mg of Fovista and Lucentis achieves superiority over Lucentis monotherapy with statistical significance on the primary endpoint in only one of our Phase 3 clinical trials and the combination of 1.5 mg of Fovista with Avastin or Eylea does not achieve superiority over Avastin or Eylea monotherapy with statistical significance on the primary endpoint in our other Phase 3 clinical trials, we likely will not receive marketing approval for Fovista.

- · If a combination of 1.5 mg of Fovista and Lucentis achieves superiority over Lucentis monotherapy with statistical significance on the primary endpoint in only one of our Phase 3 clinical trials and the combination of 1.5 mg of Fovista with Avastin or Eylea achieves superiority over Avastin or Eylea monotherapy with statistical significance on the primary endpoint in our other Phase 3 clinical trial, the FDA or similar regulatory authorities outside the United States may nonetheless not grant marketing approval for Fovista.
- Even if a combination of 1.5 mg of Fovista and an anti-VEGF drug achieves superiority over an anti-VEGF drug monotherapy with statistical significance on the primary endpoint in two or all three of our Phase 3 clinical trials, the FDA or similar regulatory authorities outside the United States may nonetheless not grant marketing approval for Fovista if such regulatory authorities do not believe that the benefits offered by Fovista administered in combination with an anti-VEGF drug are clinically meaningful or that such benefits outweigh the observed or potential risks.

In the United States, Avastin and Eylea are two of the most widely used anti-VEGF drugs for the treatment of wet AMD. If a combination of 1.5 mg of Fovista with Avastin or Eylea does not achieve superiority over Avastin or Eylea monotherapy with statistical significance on the primary endpoint of mean change in visual acuity from baseline at 12 months in our Phase 3 clinical program, our ability to successfully commercialize Fovista in combination with any anti-VEGF drug could be harmed materially. In addition, any failure of Fovista administered in combination with Avastin or Eylea to achieve superiority over Avastin or Eylea monotherapy with statistical significance on the primary endpoint could cause the FDA or similar regulatory authorities outside the United States to require additional clinical trials or other research before granting marketing approval of Fovista for use in combination with any anti-VEGF drug, including Lucentis, for the treatment of patients with wet AMD. In addition, Avastin is not approved for use in treating wet AMD, either in the United States or outside of the United States, and regulatory authorities may not permit the product label for Fovista to include the use of Fovista in combination with Avastin if we were otherwise able to obtain marketing approval for Fovista for use in combination with other anti-VEGF drugs.

The protocols for our Phase 3 clinical trials and other supporting information are subject to review by the FDA and regulatory authorities outside the United States. The FDA is not obligated to comment on our protocols within any specified time period or at all or to affirmatively clear or approve our Phase 3 clinical program. We have submitted the protocols for our Phase 3 clinical trials to the FDA and have initiated the three trials in our Phase 3 clinical program in the United States without waiting for any such comments. The FDA or other regulatory authorities may request additional information, require us to conduct additional non-clinical trials or require us to modify our proposed Phase 3 clinical program, including its endpoints, patient enrollment criteria or selection of anti-VEGF drugs, to receive clearance to initiate such program or to continue such program once initiated.

Outside the United States, we have made regulatory submissions in selected countries to initiate Phase 3 clinical trials of Fovista. To date, we have obtained approval in many of these countries and have begun dosing patients in certain of those countries. In the European Union, as further described below, in addition to filing in selected countries with national competent authorities responsible for approving clinical trial applications, we have had interactions regarding our planned application for marketing approval with the EMA's CHMP, which is the committee responsible for preparing opinions on questions concerning medicines for

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human use. The national competent authorities may follow the advice described below of the CHMP that we consider toxicity studies with Fovista administered in combination with Avastin or Eylea prior to initiating our corresponding Phase 3 clinical trial.

We may not receive clearance from regulatory authorities in jurisdictions outside the United States to initiate our Phase 3 clinical program in those jurisdictions on a timely basis. In addition, any modifications to our Phase 3 clinical program for Fovista may result in our incurring increased expense or in a delay in the enrollment or completion of such program.

In the fourth quarter of 2013, the CHMP provided scientific advice on our proposed Phase 3 clinical program for Fovista and our plan to seek regulatory approval for Fovista in the European Union. As part of that scientific advice, the CHMP advised us that the planned primary endpoint for each of the Phase 3 clinical trials for Fovista, mean change from baseline in best corrected visual acuity, was acceptable. In addition, the CHMP confirmed that carcinogenicity studies are not needed for our Phase 3 clinical program. The CHMP also advised us that we should justify our proposal to initiate, at the Phase 3 clinical trial stage, certain previously untested combinations of Fovista with Avastin or Eylea, and, as described above, that we should consider conducting toxicity studies with Fovista administered in combination with Avastin or Eylea prior to initiating our corresponding Phase 3 clinical trial. In addition, the CHMP informed us that the final label for Fovista, if it receives marketing approval, may be required to specify the licensed anti-VEGF drugs that were studied in combination with Fovista, given that Avastin is not approved for intravitreal use, rather than a broad label specifying Fovista for use in combination with any anti-VEGF drug. The CHMP further advised us that there would be a requirement for additional data to bridge the results from our Phase 3 clinical trials evaluating Fovista administered in combination with Lucentis as compared to Lucentis monotherapy to the less frequent dosing regimens of Lucentis and Eylea approved in the European Union.

In the first quarter of 2014, we received written confirmation from the CHMP on these issues. The CHMP is in agreement with our plan to use the dosing schedule approved for Eylea in the European Union as the dosing schedule in our Phase 3 clinical trial for Fovista administered in combination with Eylea so that no bridging study will be needed for this combination. The CHMP has also agreed with our plan for monthly dosing in the first year in both of our Phase 3 clinical trials evaluating Fovista administered in combination with Lucentis and, for one of these trials, to slightly modify the dosing regimen in the second year so that it is consistent with the dosing schedule approved for Lucentis in the European Union. The dosing schedule for the second year in the other trial evaluating Fovista administered with Lucentis remains unchanged. Accordingly, no bridging study will be needed and our anticipated timing and overall expense of our Phase 3 clinical plan, including our plan to have initial, top-line data from our Phase 3 clinical program for Fovista available in 2016, remains unchanged.

Although our plans reflect our current expectations regarding the endpoints, duration and number of patients to be included in our planned Phase 2/3 clinical trial evaluating Zimura for the treatment of geographic atrophy, we have only had preliminary discussions with regulatory authorities regarding our trial design. As we continue these discussions, our plans may change significantly based on feedback from such regulatory authorities. We expect that we will be required by regulatory authorities to conduct additional clinical trials of Zimura prior to seeking marketing approval in this indication.

If we are required to conduct additional clinical trials or other testing of Fovista, Zimura or any other product candidate that we may develop beyond those that we contemplate, 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 or 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.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

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We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- · clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- · regulators or institutional review boards 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 trial sites;
- · we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- $\cdot$   $\;$  the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates, such as the anti-VEGF drugs we need to use in combination with Fovista, may become insufficient or inadequate.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate new or continue ongoing clinical trials for Fovista, Zimura or any other product candidate that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as Fovista and Zimura, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors, including:

- · severity of the disease under investigation;
- · the ability of current technology to adequately define the disease state;
- · eligibility criteria for the study in question;
- · perceived risks and benefits of the product candidate under study;
- · efforts to facilitate timely enrollment in clinical trials;
- · patient referral practices of physicians;

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- the ability to monitor patients adequately during and after treatment; and
- · proximity and availability of clinical trial sites for prospective patients.

Additional financing under the Novo Agreement is contingent upon enrolling specified numbers of patients in our Phase 3 clinical trials of Fovista and our satisfying additional closing conditions and other obligations. Novo A/S will not be required to provide the additional royalty financing unless we enroll the specified numbers of patients. The Novartis Agreement also contains provisions for milestone payments by Novartis upon our achievement of certain levels of patient enrollment. We will not be entitled to receive such milestone payments unless and until we enroll the specified number of patient. In addition, our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays in our clinical trials, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials also may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of Fovista, Zimura or any other product candidate that we may develop, we may need to abandon or limit our development of Fovista, Zimura or any other product candidate.

If Fovista, Zimura or any other product candidates we may develop are associated with serious adverse events or undesirable side effects in 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. Although Fovista administered in combination with Lucentis was generally well tolerated in our Phase 1 clinical trial and our Phase 2b clinical trial, we have no clinical safety data on patient exposure to Fovista administered in combination with Lucentis for longer than 24 weeks, and we have no clinical safety data on the effects of Fovista when administered in combination with Avastin or Eylea. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. Our Phase 3 clinical program for Fovista involves the administration of Fovista in combination with anti-VEGF drugs, and the safety results of our trials are dependent, in part, on the safety and tolerability of the anti-VEGF drug administered in combination with Fovista. Avastin is not approved for the treatment of wet AMD, and according to third-party clinical trials, may be associated with a greater risk of serious adverse events or undesirable side effects as compared to Lucentis. Furthermore, we have very limited data regarding the safety and efficacy of Zimura for the treatment of geographic atrophy. In addition, we have no preclinical or clinical data on the effects of Zimura when administered in combination with both Fovista and an anti-VEGF drug.

Even if Fovista, Zimura or any other product candidate that we may develop 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 products and product candidates may be smaller than we estimate.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for wet AMD, including Lucentis, Eylea and low cost, off-label use of Avastin, are well established in the medical community, and doctors may continue to rely on these treatments without Fovista. If Fovista does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of Fovista, Zimura or any other product candidate that 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 on the use of our products in combination with other medications, such as a Fovista label requiring a waiting period after the intravitreal injection of the anti-VEGF drug and prior to the intravitreal injection of Fovista;
- · any restrictions on the use of our products to a subgroup of patients, such as by excluding from the Fovista label patients with pure occult subtype wet AMD;
- · restrictions in the label on the use of Fovista with a particular anti-VEGF drug;
- · any changes in the dosing regimen of, or the means of administering or delivering, an anti-VEGF drug with which Fovista will be used;

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- · our and our commercialization partners' ability to offer our products at competitive prices, particularly in light of the additional cost of Fovista together with an anti-VEGF drug;
- · availability of third-party coverage and adequate reimbursement, particularly by Medicare given our target market for persons over age 55;
- · willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, particularly in light of the existing available standard of care;
- · prevalence and severity of any side effects;
- whether competing products or other alternatives are more convenient or easier to administer, including whether co-formulated alternatives, alternatives that can be co-administered in a single syringe or alternatives that offer a less invasive method of administration than intravitreal injection come to market; and
- the strength of our marketing and distribution support and that of Novartis, our partner for commercialization outside of the United States.

In addition, the potential market opportunity for Fovista is difficult to estimate precisely. If Fovista receives marketing approval for the treatment of wet AMD, it will be approved solely for use in combination with an anti-VEGF drug. The market opportunity for Fovista will be dependent upon the

continued use of anti-VEGF drugs in the treatment of wet AMD and the market share of such anti-VEGF drugs for which Fovista is approved as a combination therapy. In addition, because physicians, patients and third-party payors may be sensitive to the addition of the cost of Fovista to the cost of treatment with anti-VEGF drugs, we may experience downward pressure on the price we can charge for Fovista.

Our Phase 3 clinical program enrolls patients based on a specific definition of the presence of neovascularization with certain characteristics using the commonly employed modality of optical coherence tomography, or OCT. We are not aware of any third-party clinical trials that have used this criteria to assess patient inclusion and as such do not know the proportion of total cases of subfoveal choroidal neovascularization that are represented using this specific definition of OCT guided inclusion criteria. Therefore, we cannot easily assess the impact on the potential market opportunity should Fovista receive marketing approval and the approved label exclude patients based on this criteria.

Our Phase 3 clinical program provides for a 30-minute delay in the injection of Fovista after the anti-VEGF drug to minimize the risk in our clinical trials of an unacceptable increase in intraocular pressure as a result of the amount of the two agents injected. If Fovista receives marketing approval for the treatment of wet AMD and the approved label requires such a waiting period, the potential market opportunity for Fovista may be limited to the extent that physicians and patients find such a waiting period unacceptable. Our ability to develop, acquire or in-license viable drug delivery technologies or our or Novartis's ability to develop methods for co-formulation may be limited, and we and Novartis may not be able to respond adequately to the competitive dynamics within the wet AMD treatment market.

The current standard of care for wet AMD is monotherapy administration of anti-VEGF drugs, principally Avastin, Lucentis and Eylea, which are well established therapies and are widely accepted by physicians, patients and third-party payors. When used for the treatment of wet AMD, Avastin is inexpensive. Physicians, patients and third-party payors may not accept the addition of Fovista to their current treatment regimens for a variety of potential reasons, including:

- · if they do not wish to incur the additional cost of Fovista;
- · if they perceive an additional injection to administer Fovista as undesirable and we and Novartis are unsuccessful in developing and marketing a co-formulated product;
- · if they perceive the addition of Fovista to be of limited benefit to patients; or
- · if they wish to treat with anti-VEGF drugs as monotherapy first and add Fovista only if and when resistance to continued anti-VEGF therapy limits further enhancement of visual outcome with anti-VEGF monotherapy.

Our estimates of the potential market opportunity for each of Fovista and Zimura include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate,

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then the actual market for Fovista or Zimura could be smaller than our estimates of our potential market opportunity. If the actual market for Fovista or Zimura is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

We face substantial competition, which may result in others discovering, 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 Fovista and Zimura from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of wet AMD or other disease indications for which we may develop Fovista. Although there are currently no therapies approved by the FDA or the EMA for the treatment of dry AMD, there are also a number of pharmaceutical and biotechnology companies that are currently pursuing the development of products for this indication. 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 other products or product candidates that we may seek to develop or commercialize in the future for the treatment of wet AMD, dry AMD or other diseases.

There are also a number of products in preclinical research and clinical development by third parties to treat wet AMD, including product candidates that inhibit the function of platelet derived growth factor, or PDGF, the molecule whose function Fovista also inhibits, product candidates that inhibit the function of both VEGF and PDGF that could obviate the separate use of an anti-PDGF agent, such as Fovista, and anti-VEGF gene therapy products that may substantially reduce the number and frequency of intravitreal injections when treating wet AMD. These companies include pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Regeneron Pharmaceuticals, Inc., which is working in collaboration with Bayer HealthCare, Allergan, Inc., Xcovery Vision LLC, Santen, Neurotech Pharmaceuticals, Inc., Avalanche Biotechnologies, Inc., Somalogic, Inc. and others. In addition, other companies are undertaking efforts to develop technologies to allow for a less frequent dosing schedule for anti-VEGF therapies that are currently in use. If such technologies are successfully developed and approved for use, we may need to conduct additional clinical trials of Fovista using a less frequent dosing schedule we are currently using in our ongoing Phase 3 clinical program. Any such trials may not be successful.

Moreover, there are a number of products in preclinical research and clinical development by third parties to treat dry AMD, including product candidates that are designed to suppress inflammation, such as complement system inhibitors and coricosteroids, visual cycle modulators, antioxidants and neuroprotectants, cell and gene therapies and vascular enhancers. These companies include pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes. In particular, with respect to complement system inhibition, these companies include Genentech, Novartis's Alcon division, Alexion Pharmaceuticals, Inc. and MophoSys. Moreover, we are aware that the following companies are pursuing the clinical development of ophthalmic product candidates with other mechanisms of action for the treatment of dry AMD: Alimera Sciences, Acucela, Colby Pharmaceuticals, Allergan, Pfizer, GlaxoSmithKline and Macuclear.

See "Business—Competition" in our Annual Report on Form 10-K for 2013, filed with the SEC on March 11, 2014, for more information regarding potential competitive products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to use or are less expensive than Fovista, Zimura or other products that we may develop. The commercial opportunity for Fovista also could be reduced or eliminated if our competitors develop and commercialize products that reduce or eliminate the use of anti-VEGF drugs for the treatment of patients with wet AMD. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, 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. We expect that if Fovista is approved, the cost of treatment of wet AMD with a combination of Fovista with an anti-VEGF drug will be significantly higher than the cost of treatment of wet AMD with Avastin, Lucentis or Eylea monotherapy. Insurers and other third-party payors may encourage the use of anti-VEGF drugs as monotherapy and discourage the use of Fovista in combination with these drugs. This could limit sales of Fovista.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we

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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 scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We have no experience manufacturing Fovista or Zimura at commercial scale. As a result, delays in regulatory approval of Fovista or Zimura may occur. Also, manufacturing issues may arise that could cause delays or increase costs.

We have no experience manufacturing the chemically synthesized aptamers comprising the active pharmaceutical ingredients, or API, of Fovista or Zimura at commercial scale. We currently rely on a single third-party manufacturer to supply us with API, also referred to as drug substance, for both Fovista and Zimura and a different, single third-party manufacturer to provide fill-finish services for both Fovista and Zimura. Other than our agreement with Agilent Technologies with respect to our clinical supply of Fovista API, all of our manufacturing arrangements are on a purchase order basis. In order to obtain regulatory approval for Fovista or Zimura, these third-party manufacturers will be required to consistently produce the API used in Fovista or Zimura in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so. This is referred to as process validation. If the third-party manufacturers are unable to satisfy this requirement, our business will be materially and adversely affected.

Our third-party manufacturer of API for Fovista and Zimura has made only a limited number of lots of Fovista and Zimura to date and has not made any commercial lots. The manufacturing processes for Fovista and Zimura have never been tested at commercial scale, and the process validation requirement has not yet been satisfied for either product candidate. These manufacturing processes and the facilities of our third-party manufacturers, including our third-party API manufacturer and our third-party manufacturer providing fill-finish services, will be subject to inspection and approval by the FDA before we can commence the manufacture and sale of Fovista or Zimura, and thereafter on an ongoing basis. Our third-party manufacturer for API has never been inspected by the FDA and has not been through the FDA approval process for a commercial product. Our third-party manufacturer providing fill-finish services is subject to FDA inspection from time to time. Failure by 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 regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. Based on the severity of the regulatory action, our clinical or commercial supply of API or our fill-finish services could be interrupted or limited, which could have a material adverse effect on our business.

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 other countries, do not apply to oligonucleotides, including aptamers. As a result, there is no established generally accepted manufacturing or quality standard for the production of Fovista or Zimura. Even though the FDA has reviewed the quality standards for Fovista to be used in our Phase 3 clinical program, the FDA has the ability to modify these standards at any time and foreign regulatory agencies may impose differing quality standards and quality control on the manufacture of Fovista. The lack of uniform manufacturing and quality standards among regulatory agencies may delay regulatory approval of Fovista or Zimura.

Also, as we or any manufacturer we engage scales up manufacturing of any approved product, we may encounter unexpected issues relating to the manufacturing process or the quality, purity and stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Resolving these issues could result in significant delays and may result in significantly increased costs. If we experience significant delays or other obstacles in producing any approved product for commercial scale, our ability to market and sell any approved products may be adversely affected and our business could suffer.

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 Fovista, Zimura or any other product candidate that we develop if and when Fovista, Zimura or any other product candidate is approved.

We do not have a sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. 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. If Fovista receives marketing approval, we plan to commercialize it in the United States with our own focused, specialty sales force targeting retinal specialists. Pursuant to the Novartis Agreement, we have granted to Novartis the exclusive right to commercialize Fovista outside of the United States in consideration for royalties on any such sales.

There are risks involved with establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a 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

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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;
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- · unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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 establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

If we do not maintain a successful collaborative relationship with Novartis, to whom we have granted exclusive commercialization rights for Fovista outside of the United States, or if Novartis is unable to meets its contractual obligations, we may be forced to focus our efforts internally to commercialize Fovista outside of the United States without the assistance of a commercialization partner or seek another commercialization partner, either of which would result in us incurring greater expenses and could cause a delay in market penetration while we expand our commercial operations or seek an alternative commercialization partner. Such costs may exceed the increased revenues we would receive from direct Fovista sales outside of the United States, at least in the near term. We would also be forced to declare a breach of the Novartis Agreement and seek a termination of the agreement which could result in an extended and uncertain dispute with Novartis, including arbitration or litigation, any of which will be costly.

Even if we are able to commercialize Fovista, Zimura or any other product candidate that we may develop, the product may become subject to unfavorable pricing regulations, 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. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our or our commercialization partners' commercial launch of the product, possibly for lengthy time periods, and 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.

Our ability and the ability of our commercialization partners, including Novartis, to commercialize Fovista, Zimura or any other 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 administration 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. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for Fovista, Zimura or any other product that we commercialize or our commercialization partners commercialize on our behalf, and, even if these are available, the level of reimbursement may not be satisfactory.

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 and because, in the case of Fovista, our drug will be administered in combination with other drugs that may carry high prices. In addition, physicians, patients and third-party payors may be sensitive to the addition of the cost of Fovista to the cost of treatment with anti-VEGF drugs. We or our commercialization partners may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies, including in the case of Fovista, relative to monotherapy with anti-VEGF drugs. If coverage

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and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize Fovista, Zimura or any other 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. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our and our commercialization partners' 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 ability to raise capital needed to commercialize products and our overall financial condition.

Our strategy of obtaining rights to complementary products, product candidates or technologies for the treatment of a range of ophthalmic diseases through in-licenses and acquisitions may not be successful.

We plan to expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates or technologies for the treatment of ophthalmic diseases. Because we expect generally that we will not engage in early stage research and drug discovery, the future growth of our business will depend in significant part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the rights to the relevant complementary product, product candidate or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our business, financial condition and prospects for growth could suffer.

Product liability lawsuits against us or our commercialization partners could divert our 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 Fovista, Zimura and any other product candidate that we develop in human clinical trials and we and our commercialization partners will face an even greater risk if we commercially sell any products that we develop or inlicense. Because our Phase 3 clinical program for Fovista involves the administration of Fovista in combination with anti-VEGF drugs, including off-label use by intravitreal injection of Avastin provided by us, we also face an inherent risk of product liability exposure related to the testing of such anti-VEGF drugs. If we become subject to or otherwise cannot successfully defend ourselves against claims that our product candidates, anti-VEGF drugs administered in combination with 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;
- · injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- · significant costs to defend the related litigation;
- · substantial monetary awards to trial participants or patients;
- · loss of revenue;

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- · 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 Fovista, Zimura or any other product candidate that receives marketing approval. 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. In addition, if Novartis or one of our other future commercialization or collaboration partners were to become subject to product liability claims or were unable to successfully defend themselves against such claims, any such commercialization or collaboration partners could be more likely to terminate such relationship with us and therefore substantially limit the commercial potential of our products.

# Risks Related to Our Dependence on Third Parties

We may enter into collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If either of Fovista or Zimura receives marketing approval, we plan to commercialize such product candidate in the United States with our own focused, specialty sales force targeting retinal specialists. In May 2014, we entered into the Novartis Agreement pursuant to which we granted Novartis the exclusive right to commercialize Fovista outside of the United States. We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to commercialize Zimura in markets outside the United States. We also may seek third-party collaborators for development and commercialization of other product candidates we may develop. 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 do enter into any additional arrangements with third parties in the future, we will 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 and our arrangement with Novartis for Fovista will depend on our collaborators' and Novartis's abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates, including our collaboration with Novartis, could pose numerous risks to us, including the following:

- 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 deemphasize 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, product and product candidate priorities or available funding;
- · 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;
- · we could grant exclusive rights to our collaborators, which would prevent us from collaborating with others;
- · disagreements or disputes with collaborators, including disagreements or disputes over proprietary rights, contract interpretation or the preferred course of development, 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 be expensive;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

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- 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; and
- collaborations may be terminated for 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, including Novartis, were to be involved in a business combination, the foregoing risks would be heightened, and the business combination 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, including Novartis, terminates its agreement with us, we could find it more difficult to attract new collaborators and the perception of our company in the business and financial communities 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 will depend heavily on our commercialization arrangement with Novartis for Fovista outside of the United States. If Novartis terminates our agreement or is unable to meet its contractual obligations, it could negatively impact our revenues and harm our business until appropriate measures have been taken.

On May 19, 2014, we entered into the Novartis Agreement pursuant to which we granted exclusive rights to Novartis to commercialize Fovista outside of the United States. The agreement continues until the date on which we are no longer entitled to receive a royalty on Fovista or any co-formulated product containing Fovista developed under the agreement. The agreement is subject to early termination in the event of certain customary defaults, such as material breach of the agreement and bankruptcy. In addition, the agreement is subject to early termination by either us or Novartis if the other party challenges or assists a third party in challenging the validity or enforceability of certain patent rights controlled by the terminating party, or if the parties are prevented in any manner that materially adversely affects the progression of the development or commercialization of licensed products for a specified period as a result of specified governmental actions. Novartis may also terminate the agreement at any time without cause, or within a specified period after a change in control of us, as defined in the agreement, or for specified safety reasons, effective at the end of a specified period following Novartis's written notice to us of Novartis's election to terminate the agreement. We may also terminate the agreement if Novartis determines to seek marketing approval of an alternative anti-PDGF product outside the United States. If we do not maintain a successful collaborative relationship with Novartis or if Novartis is unable to meet its contractual obligations or if there is an early termination of the agreement as described above, we will be forced to either establish a commercial infrastructure outside of the United States so that we could undertake the commercialization efforts which had been theretofore undertaken by Novartis or we will need to seek an alternative partner. The establishment of a commercial infrastructure and assumption by us of commercialization activities outside of the United States would require substantial resources, financial and otherwise, and could result in us incurring greater expenses than the increase in revenues from our direct sales of Fovista. It could also cause a delay in market penetration while we expand our commercial operations. Seeking and obtaining an alternative commercial partner outside the United States could also result adversely impact sales of Fovista and market penetration outside of the United States.

# If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of Zimura and other product candidates that we may develop will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the

proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, 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, 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, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product

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

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 our product candidates or bring them to market and generate product revenue.

We rely on third parties in conducting our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have relied on third-party clinical research organizations, or CROs, in conducting our completed clinical trials of Fovista and Zimura. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, in conducting our clinical trials for Fovista and Zimura, including the clinical trials in our Phase 3 clinical program for Fovista, and expect to rely on these third parties to conduct clinical trials of any other product candidate that we may develop. 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, that would delay our product development activities.

Our reliance on these third parties for 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 requires us to comply with standards, commonly referred to as Good Clinical Practices, or 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 a government-sponsored database within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

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

We contract with third parties for the manufacture of both Fovista and Zimura for clinical trials and expect to continue to do so in connection with the commercialization of Fovista and for clinical trials and commercialization of any other product candidates that we develop or may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of Fovista or Zimura and have limited personnel with manufacturing experience. We currently rely on and expect to continue to rely on third-party contract manufactures to manufacture clinical and commercial supplies of Fovista and Zimura, preclinical and clinical supplies of other product candidates we may develop and commercial supplies of products if and when approved for marketing by applicable regulatory authorities. Our current and anticipated future dependence upon others for the manufacture of Fovista, Zimura and any other product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Under the Novartis Agreement, we are responsible for supplying to Novartis drug substance for Fovista for clinical and commercial supply.

We currently rely exclusively on a single third-party manufacturer to provide clinical supplies of both Fovista drug substance and Zimura drug substance. We also engage a single third-party manufacturer to provide fill-finish services for clinical supplies of both Fovista and Zimura. Other than our agreement with Agilent Technologies with respect to our clinical supply of Fovista drug substance, we obtain these supplies and services from each of these manufacturers on a purchase order basis. We do not currently have

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any contractual commitments for commercial supply of bulk drug substance for either Fovista or Zimura or for fill-finish services. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for Fovista or Zimura or for fill-finish services. The prices at

which we are able to obtain supplies of drug substance for Fovista or Zimura and fill-finish services may vary substantially over time and adversely affect our financial results. Furthermore, we currently rely on sole-source suppliers of certain raw materials and other specialized components of production used in the manufacture and fill-finish of each of Fovista and Zimura.

We currently rely exclusively on Nektar to supply us with a proprietary polyethylene glycol, or PEG, reagent for Fovista under a manufacturing and supply agreement. PEG reagent is a chemical we use to modify the chemically synthesized aptamer in Fovista. The PEG reagent made by Nektar is proprietary to Nektar and, to our knowledge, is not currently available from any other third party.

We obtain a different proprietary PEG reagent used to modify the chemically synthesized aptamer in Zimura from a different supplier on a purchase order basis. We do not currently have any contractual commitments for supply of the PEG reagent we use for Zimura.

If our third-party manufacturers for Fovista drug substance, Zimura drug substance or the PEG reagent we use for Zimura fail to fulfill our purchase orders, if Nektar breaches its obligations to us under our supply agreement, or if any of these manufacturers should become unavailable to us for any reason, we believe that there are a limited number of potential replacement manufacturers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We could also incur additional costs and delays in identifying or qualifying a replacement manufacturer for fill-finish provider should become unavailable for any reason. We may be unable to establish any agreements with such replacement manufacturers or fill-finish providers or to do so on acceptable terms.

Under the supply agreement with Nektar, we must purchase our entire requirements for PEG reagent for Fovista exclusively from Nektar at an agreed price. In the event Nektar breaches its supply obligations as specified in the agreement, Nektar has agreed to enable a third-party manufacturer, if one is available, to supply us with PEG reagent until Nektar demonstrates that Nektar has the ability to supply all of our requirements for PEG reagent. The agreement of Nektar to enable a third-party manufacturer may be difficult to enforce in the context of a breach by Nektar of its supply obligations. We may not be able to reach an agreement with any third-party manufacturer to take on the supply of PEG reagent under such circumstances because, to our knowledge, no third party currently manufactures the PEG reagent we currently use in making the Fovista drug substance. Furthermore, the third party's right to supply us with PEG reagent would be subject to termination at any time once Nektar demonstrates that Nektar has the ability to supply all of our requirements for PEG reagent, which may limit the interest of potential third-party manufacturers in undertaking such an engagement. In addition, the process of transferring any necessary technology or process to a third-party manufacturer would entail significant delay in or disruption to the supply of PEG reagent and, as a result, a significant delay in or disruption to the manufacture of Fovista. Furthermore, the FDA or other regulatory authorities might require additional studies to demonstrate equivalence between the Fovista drug substance made using the Nektar PEG reagent and the Fovista drug substance made using any replacement PEG reagent we propose to use to make Fovista. We ultimately may be unable to demonstrate such equivalence.

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

- Fovista, Zimura and any other product that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- · reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible breach of our supply obligations to Novartis;
- · the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- · the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. 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

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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 depend on licenses and sublicenses for development and commercialization rights to our products, product candidates and technologies. Termination of these rights or the failure by us or our licensees, including our commercialization or collaboration partners to comply with obligations under these or other agreements under which we obtain such rights or have obtained funding could materially harm our business and prevent us from developing or commercializing our products and product candidates.

We are party to various agreements, including an acquisition agreement with OSI Pharmaceuticals and license agreements with Archemix and Nektar that we depend on for rights to Fovista, Zimura and other product candidates and technology. These agreements impose, and we may enter into additional licensing arrangements or other agreements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our acquisition agreement with OSI Pharmaceuticals and our licensing agreement with Nektar, we are obligated to pay royalties on net product sales of Fovista or other product candidates or related technologies to the extent they are covered by the agreement. Under our license agreements with Archemix and Nektar, we 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.

We also have diligence and development obligations under our acquisition agreement with OSI Pharmaceuticals and our license agreements with Archemix and Nektar. Generally, these diligence obligations require us to use commercially reasonable efforts to develop, seek regulatory approval for and commercialize our products in the United States, the European Union and, in some cases, certain other specified countries. Although the Novartis Agreement

provides that Novartis will be responsible for performing certain of these obligations with respect to specified countries, we still remain liable under our agreements with OSI Pharmaceuticals, Archemix and Nektar. If we fail to comply with our obligations under current or future acquisition, license and funding agreements, or otherwise breach an acquisition, license or funding 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. Such a failure to comply or breach by us under any of these agreements could also lead to a breach by us of the Novartis Agreement. 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 Fovista, Zimura and other important intellectual property or technology. Any of the foregoing could prevent us from commercializing Fovista, Zimura or other product candidates we may develop, which could have a material adverse effect on our operating results and overall financial condition.

In addition to the generally applicable diligence obligations set forth above, we have specific obligations with respect to the licensing agreements described below:

- · Under the terms of the agreement with OSI Pharmaceuticals under which we acquired certain rights to develop and commercialize Fovista, if we or our commercialization or collaborative partners fail to meet certain obligations, OSI Pharmaceuticals may terminate the agreement as to such countries with respect to which such failure has occurred, and upon such termination we will be obligated to grant, assign and transfer to OSI Pharmaceuticals specified rights and licenses related to our anti-PDGF aptamer technology and other related assets, and if we are manufacturing such anti-PDGF products at the time of such termination, may be obligated to provide transitional supply to OSI Pharmaceuticals of covered anti-PDGF products, for such countries.
- Under the terms of the amended license, manufacturing and supply agreement with Nektar, pursuant to which we obtained, among other licenses, an exclusive, worldwide license to make, develop, use, import, offer for sale and sell certain products that incorporate a specified PEG reagent linked with the active ingredient in Fovista, if we fail to use commercially reasonable efforts to achieve the first commercial sale of Fovista in the United States or one of a specified group of other countries by December 31, 2017, which date Nektar and we may agree in good faith to extend in specified circumstances, Nektar may either terminate our license or convert our license for such country to a non-exclusive license. In addition, if we fail to use commercially reasonable efforts to develop Fovista and file and seek approval of NDAs on a schedule permitting us to make first commercial sales of Fovista in specified countries by December 31, 2017, do not make such first commercial sales of Fovista by such date, or thereafter fail to use commercially reasonable efforts to continue to commercialize and market Fovista in such countries, we will be in material breach of the agreement and Nektar will have the right to terminate the agreement.

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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. For example, the licenses from Archemix include sublicenses to us of rights to specified technology, which we refer to as the SELEX technology, licensed by University License Equity Holdings, Inc. to Gilead Sciences, Inc., or Gilead, and sublicensed by Gilead to Archemix, as well as other technology owned by Gilead and licensed to Archemix. In addition, the licenses we have obtained from Nektar include sublicenses of certain rights. 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 and commercialize Fovista, Zimura and other product candidates may be materially harmed and could also lead to a breach by us of the Novartis Agreement. 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.

# **Risks Related to Our Intellectual Property**

The patent prosecution process is expensive and time-consuming, is highly uncertain and involves complex legal and factual questions. Recent 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 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 our collaboration or commercialization partners may develop, the eventual commercialization of which could potentially entitle us to royalty payments. In some circumstances, our licensors 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, European patent law restricts 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 United States Patent and Trademark Office 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, validity, term, enforceability and commercial value of our patent rights are highly uncertain.

Our and our collaboration and commercialization partners' 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 our collaboration and commercialization partners may not be able to generate sufficient additional data on a timely basis, or at all. 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 our collaboration and commercialization partners' patents or narrow the scope of our or their patent protection.

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Recent 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. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, 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. 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 license, develop or commercialize current or future product candidates.

If we are unable to obtain and maintain patent protection for our technology and products during the period of their commercialization, 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.

The last to expire of the U.S. patent rights covering the composition of matter of Fovista is expected to expire in 2017. Such expiration date is not long after the date by which we expect Fovista to be commercialized in the United States if we obtain marketing approval and may even be prior to such date. We own an issued U.S. patent covering methods of treating wet AMD with Fovista in combination with Avastin or Lucentis, which is expected to expire in 2024. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent restoration term of up to five years as partial compensation for patent term effectively lost during product development and the FDA regulatory review process occurring after the issuance of a patent. We may be able to obtain a patent term extension for one of these U.S. patents. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration 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 will be shorter than we would otherwise expect, and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

The European patent rights covering the composition of matter of Fovista are expected to expire in 2018. Such expiration date is shortly after the date by which we expect Fovista to be commercialized in Europe, and may even be prior to such date. We own a granted European patent covering a combination of Fovista and Lucentis or Avastin for use in a method for treating wet AMD. This European patent is expected to expire in 2024.

We also have filed in the United States patent applications covering a method of treating wet AMD in patients with Fovista in combination with Eylea and in Europe and Japan a patent application covering a combination of Fovista and Eylea for use in a method for treating wet AMD. These patent applications are in the early stages of prosecution and may not result in patents being issued which protect the use of Fovista in combination with Eylea for treating wet AMD or effectively prevent others from commercializing competitive technologies and products. If a patent is granted following prosecution of any such application, that patent would be expected to expire in 2030.

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 use of a product directed by off-label prescriptions 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 active pharmaceutical ingredient as Fovista, Zimura or any other product candidates we may develop would limit our ability to generate revenue from the sale of Fovista, Zimura or such other product candidates, if approved for commercial sale. In addition, European patent law generally makes the issuance and enforcement of patents that cover methods of treatment of the human body difficult. Further, once the composition-of-matter patents relating to Fovista, Zimura or any other product candidate in a particular jurisdiction, if any, expire, competitors will be able to make, offer and sell products containing the same active pharmaceutical ingredient as Fovista, Zimura or such other product candidate in that jurisdiction so long as these competitors do not infringe any other of our patents covering Fovista's or Zimura's composition of matter or method of use or manufacture, do not violate the terms of any marketing or data exclusivity that may be granted to us by regulatory authorities and 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 active pharmaceutical ingredient as Fovista or Zimura in combination with any anti-VEGF drug, even if such use infringes any of our method-of-treatment patents.

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 under which we are licensed without infringing such patents. This might enable our competitors to develop during the lifetime of these patents drugs that compete with Fovista or Zimura, if approved.

The U.S. patent rights covering Zimura as a composition of matter are expected to expire in 2025. Such expiration date may be prior to the date by which we would be able to commercialize Zimura in the United States if we seek and obtain marketing approval. The U.S. patent rights covering methods of treating certain complement protein mediated disorders with Zimura are expected to expire in 2026. As a result, if we obtain marketing approval for Zimura, we may not be able to exclude competitors from commercializing products similar or identical to ours if such competitors do not use or promote our claimed methods of treatment or do use or promote our methods of treatment after our patents expire. Depending on potential delays in the regulatory review process for Zimura, we may be able to obtain a patent term extension for one of these patents in the United States, but we can provide no assurances that such an extension will be obtained.

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. We could also fail to take the required actions and pay the necessary governmental fees to maintain our patents.

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 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 an attempt to prevent them from launching such generic versions. 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 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.

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. 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

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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. 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. 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 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 collaboration and commercialization 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. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We or our collaboration and commercialization partners 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, opposition, cancellation or similar proceedings before the U.S. Patent and Trademark Office or its foreign counterparts. The risks of being involved in such litigation and proceedings may also increase as our or their product candidates near commercialization and as we gain the greater visibility associated with being a public company.

Third parties may assert infringement claims against us or our collaboration or commercialization partners 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 and uses. Thus, we do not know with certainty that Fovista, Zimura or any other product candidate, or our intended commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are or one of our collaboration or commercialization partners 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 and marketing our or their products and technology or to continue using a trademark. However, we or our collaboration and commercialization partners 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 collaboration and commercialization partners and could require us or them to make substantial licensing and royalty payments. We or our collaboration and commercialization partners could be forced, including by court order, to cease 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 collaboration and commercialization partners from commercializing our or their 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 collaboration and commercialization partners 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 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 any 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 rights to Fovista from Eyetech, Archemix and Nektar and rights to Zimura from Archemix, we must rely on these parties' practices, and those of their predecessors, with regard to the assignment of intellectual property therein. 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.

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# 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.

#### 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 on 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 employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, 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. Moreover, because we acquired certain rights to Fovista from Eyetech, Archemix and Nektar, we must rely on these parties' practices, and those of their predecessors, with regard to the protection of Fovista-related trade secrets before we acquired them. 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 be able to obtain adequate remedies for such breaches. 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. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

# Risks Related to Regulatory Approval and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize Fovista, Zimura or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired.

Our product candidates, including Fovista and Zimura, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market Fovista, Zimura or any other product candidate from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs and Novartis to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that Fovista, Zimura or any other 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 or other regulatory authority may limit the approval of Fovista to use with only specified anti-VEGF drugs rather than with all anti-VEGF drugs. Such limitation could limit sales of Fovista.

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

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the product candidates involved. 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 preclinical, 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 such as Fovista and Zimura manufactured using novel 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. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions.

If we experience delays in obtaining approval or if we fail to obtain approval of Fovista, Zimura or any other product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

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.

In the United States, our lead product candidate, Fovista, received fast track designation and may be eligible for priority review status. If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for FDA fast track designation. If a drug offers major advances in treatment, the drug sponsor may apply for FDA priority review status. The FDA has broad discretion whether or not to grant fast track designation or priority review status, so even if we believe a particular product candidate is eligible for such designation or status, the FDA could decide not to grant it. Even though Fovista has received fast track designation for the treatment of wet AMD and may be eligible for priority review status, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

# $Failure\ to\ obtain\ marketing\ approval\ in\ international\ jurisdictions\ would\ prevent\ our\ product\ candidates\ from\ being\ marketed\ abroad.$

In order to market and sell Fovista, Zimura and any other product candidate that we may develop in the European Union and many other jurisdictions, we or our third-party commercialization partners, including Novartis, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. 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 approved for sale in that country. We or our third-party commercialization partners, including Novartis, may not obtain 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.

Any product candidate, including Fovista and Zimura, 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 fail to comply with regulatory requirements or if we or our third-party commercialization partners experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate, including Fovista and Zimura, 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 continual 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, quality assurance, complaints and corresponding maintenance of records and

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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.

The FDA may also impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare 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 and warnings in the labeling and marketing of a product;
- · restrictions on product distribution or use;
- · requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- · withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- · fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- · refusal to permit the import or export of our products;
- · product seizure; or
- · injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can lead to significant penalties and sanctions.

Our and our commercialization partners' relationships with customers 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, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates, including Fovista, for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us and our commercialization partners to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we 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:

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- 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 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 civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- 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 relating to healthcare matters;

- · 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;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any
  materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law and analogous state laws require manufacturers of drugs, devices, biologics and medical supplies to report information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- · analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by 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 in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, 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 providers or entities with whom we expect to do business are 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of Fovista, Zimura or any other product candidate that we may develop, restrict or regulate post-approval activities and affect our and our commercialization partners' ability to generate revenue from, sell profitably or commercialize any product candidates, including Fovista and Zimura, for which we or they obtain marketing approval or products that we may develop or in-license. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we or our commercialization partners receive for any approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products and could decrease the coverage and price that we receive for any

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approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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 PPACA. Among the provisions of PPACA of importance to our potential products are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- · an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- · expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- · a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices:
- · extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- · new requirements to report financial arrangements with physicians and teaching hospitals;
- · a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, 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. These new laws may result in additional reductions in Medicare and other healthcare funding. Additionally, current legal challenges to the PPACA could adversely affect coverage and/or reimbursement.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, or in-licensed products, if any, may be.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

The pricing of prescription pharmaceuticals is also subject to governmental control outside of the United States. 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 commercialization partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate 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 harmed, possibly materially.

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

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wastes. From time to time and in the future, our operations may 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 use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. 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.

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 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.

# Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on David R. Guyer, M.D., our Chief Executive Officer, Samir Patel, M.D., our President, and Bruce Peacock, our Chief Financial and Business Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We are rapidly expanding our development, regulatory and sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We are currently experiencing significant and rapid growth in the number of our employees and the scope of our operations, particularly in the area of clinical development. Between January 1, 2013 and June 30, 2014, we hired more than half of our 50 employees. We also expect to continue to hire additional employees and expand the scope of our operations in the area of clinical development and, as we approach potential marketing approval for any of

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#### Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders maintain the ability to significantly influence all matters submitted to stockholders for approval.

As of June 30, 2014, our executive officers, directors and principal stockholders and their affiliates, in the aggregate, beneficially owned shares representing approximately 34% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to 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. As of June 30, 2014, we had outstanding 33,452,008 shares of common stock. Of these shares, approximately 14,757,493 shares are restricted securities under Rule 144 under the Securities Act, including, for example, shares sold in our initial public offering or our follow-on public offering, may be resold in the public market without restriction unless purchased by our affiliates. Moreover, holders of an aggregate of approximately 11,305,258 shares of our common stock, including shares issuable pursuant to outstanding warrants, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In October 2013 and January 2014, we filed registration statements registering all shares of common stock that we may issue under our equity compensation plans. As of June 30, 2014, we had outstanding stock options to purchase an aggregate of approximately 3,851,000 shares of our common stock, of which options to purchase approximately 1,157,000 shares were vested. These shares can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates and the applicable lock-up agreements entered into in connection with our public offerings.

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 our current 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 the 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.

#### An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on The NASDAQ Global Select Market on September 25, 2013. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

## 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. 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. 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:

- the success of competitive products or technologies;
- · results of clinical trials of Fovista, Zimura and any other product candidate that we may develop;
- · results of clinical trials of product candidates of our competitors;
- · regulatory or legal developments in the United States and other countries;
- · developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- · the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire the rights to other products, product candidates and technologies for the treatment of ophthalmic diseases, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- · variations in our financial results or those of companies that are perceived to be similar to us;
- · changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- · general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize Fovista. Such 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.

# Commencing January 1, 2015, we will no longer be an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies will no longer apply to us.

We are currently an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. Because as of June 30, 2014, the market value of our common stock that was held by non-affiliates exceeded \$700 million, we will no longer qualify for such status commencing January 1, 2015. As a large-accelerated filer, we will be subject to certain disclosure requirements

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that are applicable to other public companies that have not been applicable to us as an emerging growth company. These requirements include:

- · compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- · compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- · full disclosure obligations regarding executive compensation; and
- · compliance with the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, we will no longer be able to take advantage of transition periods for complying with new or revised accounting standards that are available to emerging growth companies.

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

As a public company, and particularly commencing January 1, 2015 when we will no longer be an "emerging growth company," we do and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. 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 will make some activities more time-consuming and costly.

Commencing January 1, 2015, we will no longer be an emerging growth company and as such we will not be able to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are emerging growth companies as has been the case to date.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, commencing January 1, 2015, we will be required to furnish with our periodic Exchange Act reports a report by our management on our internal control over financial reporting. Commencing January 1, 2015, because we will no longer be an emerging growth company, we will be required to include with our annual report an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to 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, engage outside consultants and adopt a detailed work plan 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. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe, or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

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# 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.

#### **Use of Proceeds from Registered Securities**

On September 30, 2013, we closed our initial public offering of 8,740,000 shares of our common stock, including 1,140,000 shares of our common stock pursuant to the exercise by the underwriters of an over-allotment option, at a public offering price of \$22.00 per share for an aggregate offering price of approximately \$192.3 million. The offer and sale of all of the shares in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-190643), which was declared effective by the SEC on September 24, 2013.

We received aggregate net proceeds from our initial public offering of \$175.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

As of June 30, 2014, we have used approximately \$12.1 million of the net proceeds from initial public offering as follows:

- · approximately \$8.4 million to fund certain costs of our Phase 3 clinical program for Fovista administered in combination with anti-VEGF drugs for the treatment of wet AMD, which costs consists of external research and development expenses and clinical development related employee expenses; and
- · approximately \$3.7 million for working capital and other general corporate purposes.

We have not used any of the net proceeds from our initial public offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10% or more of our common stock or to any affiliate of ours. We have invested the remaining net proceeds from initial public offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

# Item 5. Other Information.

None.

#### Item 6. Exhibits.

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

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#### **SIGNATURES**

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

#### **OPHTHOTECH CORPORATION**

Date: August 6, 2014

By: /s/ Bruce A. Peacock

Bruce A. Peacock

Chief Financial and Business Officer

(Principal Financial and Accounting Officer)

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#### EXHIBIT INDEX

Exhibit Number	Description of Exhibit				
10.1	Clinical Manufacturing and Supply Agreement by and between the Registrant and Agilent Technologies, Inc. dated May 2, 2014				
10.2	Licensing and Commercialization Agreement by and between the Registrant and Novartis Pharma AG dated May 19, 2014				
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 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. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	XBRL Instance Document*				
101.SCH	XBRL Taxonomy Extension Schema Document*				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*				
101.LAB	XBRL Taxonomy Extension Label Linkbase Database*				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*				

<sup>\*</sup> Submitted electronically herewith.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheet at December 31, 2013 and June 30, 2014 (unaudited), (ii) Statement of Operations (unaudited) for the three month period and six month period ended June 30, 2014 and 2013 and for the period from inception (January 5, 2007) through June, 2014, (iii) Statement of Cash Flows (unaudited) for the six month period ended June 30, 2014 and 2013 and for the period from inception (January 5, 2007) through June 30, 2014 and (iv) Notes to Financial Statements (unaudited).

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.



Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

#### CLINICAL MANUFACTURING AND SUPPLY AGREEMENT

This Clinical Manufacturing and Supply Agreement (this "<u>Agreement</u>") is entered into by and between AGILENT TECHNOLOGIES, INC., a Delaware corporation, having a principal office at 5301 Stevens Creek Blvd., Santa Clara, CA 95051 ("<u>Agilent</u>") and OPHTHOTECH CORPORATION, a Delaware corporation, having a principal office at One Penn Plaza, Suite 1924, New York, NY 10119 ("Customer") effective as of May 2, 2014 (the "<u>Effective Date</u>"). Agilent and Customer are each referred to herein as a "<u>Party</u>" and together as the "<u>Parties</u>".

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

#### 1. SCOPE OF AGREEMENT

This Agreement, together with the Quality Agreement (as defined below) specifies the terms and conditions under which Agilent will manufacture and supply the Product (as defined below) to Customer and perform Manufacturing Services (as defined below) for Customer solely for clinical purposes and not for commercial purposes.

#### 2. **DEFINITIONS**

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

- 2.1 "Affiliate" means any business entity which directly or indirectly controls, is controlled by, or is under common control with any Party to this Agreement. A business entity shall be deemed to "control" another business entity if (i) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or (ii) it has the de facto ability to control or direct the management of such business entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of fifty percent (50%) or more, "control" shall be deemed to exist at the maximum level of ownership allowed by such jurisdiction; provided, however, that there is a de facto ability to direct or control its management.
- 2.2 "Anti-PDGF Aptamer" means (i) an Aptamer that binds to platelet-derived growth factor (PDGF) and (ii) intermediates thereof.
- 2.3 "Active Pharmaceutical Ingredient (API)" has the meaning set forth in the Quality Agreement.
- 2.4 "<u>Aptamer</u>" means (i) any pegylated or unpegylated naturally or non-naturally occurring oligonucleotide that binds to a Target and (ii) any pegylated or unpegylated oligonucleotide Derived from an oligonucleotide of clause (i) that binds to a Target.
- 2.5 "<u>Batch</u>" has the meaning set forth in the Quality Agreement.
- 2.6 "Batch Packet" has the meaning set forth in the Quality Agreement.
- 2.7 "Certificate of Analysis" has the meaning set forth in the Quality Agreement.
- 2.8 "Certificate of Compliance" has the meaning set forth in the Quality Agreement.
- 2.9 "Change Management" means the procedure set forth in the Quality Agreement.
- 2.10 "Commercial Supply Agreement" has the meaning set forth in Section 3.6.

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- 2.11 "<u>Derived</u>" means identified, obtained, developed, created, synthesized, designed or resulting from, based upon, containing or incorporating or generated from or conjugated to or complexed with (whether directly or indirectly or in whole or in part).
- 2.12 "<u>Facility</u>" means Agilent's manufacturing facility located at Boulder, Colorado, or such other manufacturing site agreed to by the Parties in writing.
- 2.13 "FDA" means the United States Food and Drug Administration or any successor organization.
- 2.14 "Finished Product" means Customer's biological or pharmaceutical drug product that includes the Product.
- 2.15 "GMP" has the meaning set forth in the Quality Agreement.
- 2.16 "Good Condition" means that at the time of delivery to Customer's carrier the Product supplied shall: (i) be the right Product; (ii) be in the right quantity in accordance with the manifest; (iii) be in the packaging agreed to by the Parties; (iv) be labeled in accordance with the Product registration; and (v) have no visible defect in the packaging or seal.
- 2.17 "<u>Independent Laboratory</u>" means a laboratory independent of each Party, mutually agreed in writing between the Parties and competent to determine the matters referred to in Section 8.2.3.
- 2.18 "<u>Initial Order</u>" has the meaning set forth in Section 4.1.

- 2.19 "<u>Initial Term</u>" has the meaning set forth in Section 13.1.
- 2.20 "Intellectual Property" means, collectively, Patents, Marks, copyrights, Know-How, and any other intellectual property owned or licensed by a Party.
- 2.21 "Kilos" means kilos of oligo weight.
- 2.22 "Know-How" means all non-patented and proprietary: information, inventions, developments, techniques, materials, processes, manufactures, compositions of matter or methods of use and trade secrets, whether or not patentable or copyrightable. Know-How excludes (i) Patents and (ii) any of the foregoing which would be excluded from the definition of Proprietary of Information under Section 5 of the Confidentiality Agreement.
- 2.23 "Latent Defect" means a failure of Product to meet the Specification at the time of delivery, which failure is subsequently detected and (i) is not attributable to a defect in the PEG delivered to Agilent by Customer for use in the Product, which defect in the PEG was not discoverable by Agilent in the course of testing in accordance with Agilent's Standard Operating Procedure; (ii) is not attributable to a fundamental chemical or stability defect in the Product that results in a change in the Product that occurs after delivery by Agilent; and (iii) is not the result of further processing, storage, handling or use of the Product after delivery by Agilent.
- 2.24 "<u>Licensed Patent(s)</u>" means any Patent owned by Agilent as of the Effective Date or during the Term claiming or covering the Process.
- 2.25 "<u>Manufacturing Services</u>" means those manufacturing services set forth in a Statement of Work to be performed by Agilent with respect to Product and Finished Product, including the development and validation of analytic methods, stability testing and release.
- 2.26 "Manufacturing Standards" has the meaning set forth in Section 5.2.
- 2.27 "<u>Marks</u>" means the trademarks, service marks, trade dress, trade names, logos, insignia, symbols, designs or other marks identifying either Party or its products.
- 2.28 "Master Batch Record" has the meaning set forth in the Quality Agreement.

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- 2.29 "<u>Patents</u>" means patents, patent applications and any issued divisions, continuations, continuations-in-part, re-issues, re-examinations, renewals or extensions thereof and any foreign counterpart of any of such U.S. patents.
- 2.30 "Person" means any individual, partnership, corporation, limited liability company, unincorporated organization or association, any trust or any other business entity.
- 2.31 "Process" or "Processing" means the combination of materials, procedures, test methods and controls used by Agilent to manufacture the Product under this Agreement, that includes the following unit operations: [\*\*].
- 2.32 "Product" means (i) the Aptamer described in Exhibit A and intermediates thereof, and (ii) any future compounds as mutually agreed to by the Parties in a written amendment to this Agreement.
- 2.33 "Proprietary Information" has the meaning set forth in Section 14.1.1.
- 2.34 "<u>Purchase Order</u>" means a written purchase order in substantially the form agreed in good faith based on customary arrangements in the biotechnology industry between Agilent and Customer, to be delivered by Customer to Agilent for Product or services pursuant to this Agreement.
- 2.35 "Quality Agreement" means the agreement by and between Agilent and Customer, dated as of the Effective Date, executed by duly authorized representatives of each Party, setting forth the obligations of the Parties with respect to quality matters applicable to the manufacturing and supply of the Product and Customer's drug product testing under this Agreement, attached hereto as Exhibit C.
- 2.36 "Regulatory Authority" has the meaning set forth in the Quality Agreement.
- 2.37 "Renewal Term" has the meaning set forth in Section 13.1.
- 2.38 "<u>Specification</u>" means the specification for the Product as set forth in a Statement of Work, which specification may be amended from time to time in accordance with this Agreement.
- 2.39 "Statement of Work" means (i) any of the statements of work identified in Exhibit E; and (ii) any future statement of work as mutually agreed to by the Parties.
- 2.40 "Target" means a protein, cytokine, enzyme, receptor, transducer, transcription factor, antigen or any other non-nucleic acid molecule.
- 2.41 "<u>Term</u>" has the meaning set forth in Section 13.1.
- 2.42 "Third Party" means any Person who is not a Party or an Affiliate of a Party.

## 3. OBLIGATIONS OF THE PARTIES; STATEMENTS OF WORK

3.1 <u>Obligations of Agilent</u>. Agilent will manufacture and supply the Product to Customer and perform the Manufacturing Services at the Facility in accordance with the terms of this Agreement, the Quality Agreement, any applicable Statement of Work and in accordance with

GMP and all laws and regulations applicable to the manufacture and supply of the Product at the Facility and the performance of the Manufacturing Services. Agilent shall perform the Manufacturing Services in a professional and workmanlike manner consistent with industry standards. Agilent will deliver the Product in accordance with the delivery schedules set forth in, as applicable, the Initial Order and each subsequent accepted Purchase Order.

3.2 <u>Obligations of Customer</u>. Customer will provide Agilent with information, material and cooperation reasonably necessary for the manufacture and supply of the Product in accordance with the Statement of Work and the Quality Agreement.

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- 3.3 PEG Supply Agreement. Without limiting the generality of Section 3.2, during the Term, Customer shall use commercially reasonable efforts to maintain the License, Manufacturing and Supply Agreement between Customer and Nektar Therapeutics, Corporation ("Nektar"), dated September 30, 2006, as amended, (the "PEG Supply Agreement"), or enter into an agreement with Nektar or another Third Party to obtain supply of poly ethylene glycol ("PEG") for the E10030 molecule. For purposes of clarity, Customer may terminate the PEG Supply Agreement with Nektar; provided that Customer has obtained an alternative source of supply of PEG and provided further that Agilent shall not be liable for any delays or supply failures associated with such termination and retention of an alternative source of supply of PEG. Customer shall reimburse Agilent for any reasonable direct costs incurred by Agilent to qualify any alternative source of supply of PEG. Customer and Agilent shall cooperate to ensure that Customer's orders of PEG to be delivered to Agilent from Nektar (or such alternative Third Party) are (i) in sufficient amounts to enable Agilent to manufacture Product ordered by Customer hereunder; and (ii) in conformance with the forecasting and order procedure set forth in the PEG Supply Agreement. During the Term, Customer shall provide Agilent copies of proposed forecasts for PEG (redacted to remove confidential information or commercially sensitive information) at the time of submission to Nektar (or such alternative Third Party). Within [\*\*] business days after receipt of any such PEG forecast, Agilent shall provide written notice to Customer of any adjustments to such forecast that Agilent reasonably deems necessary in order to ensure a supply of PEG necessary to manufacture Product to fulfill Customer's requirements of Product hereunder. Within [\*\*] business days after receipt of written notice from Agilent, Customer shall provide Agilent with written confirmation (which may be by e-mail) that either (i) Customer has submitted a forecast revised pursuant to Agilent's notice and whether Nektar has accepted such revised forecast, or (ii) Customer does not agree such revised forecast is required in which case the Parties will meet to determine what adjustments, if any, are required to the forecast and upon such determination Customer shall submit such revised forecast to Nektar if so agreed by the Parties.
- Statements of Work. From time to time during the Term, Customer may request that Agilent perform certain Manufacturing Services for the Product. As mutually agreed by the Parties in a Statement of Work, each Party shall perform the obligations set forth in each Statement of Work. In the event of any inconsistency between this Agreement and a Statement of Work, the terms and conditions of this Agreement shall prevail. Each Party shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform such obligations in accordance with this Agreement. Agilent may, with the prior written consent of Customer, subcontract or delegate its obligations under this Agreement to perform the services; provided, that any subcontractor shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Statement of Work. Customer and Agilent acknowledge and agree that the Statements of Work entered into prior to the Effective Date and identified in Exhibit E and the Initial Orders shall be governed by the terms and conditions of this Agreement and that references to the Agilent supply and service agreement terms and conditions in such Statements of Work shall be deemed references to this Agreement.

# 3.5 <u>Exclusivity</u>.

- 3.5.1 Except as otherwise provided in Section 13.3.1, Agilent agrees that (a) during the Term and (b) provided that the Commercial Supply Agreement is in effect between the Parties, for a five (5) year period after the Term (the "Exclusivity Period"), Agilent shall only supply Anti-PDGF Aptamer APIs or Finished Product to Customer and any Affiliate of Customer or Third Party designated by Customer.
- 3.5.2 Customer agrees that during the Term, Agilent shall be Customer's supplier of at least [\*\*] percent ([\*\*]%) of Customer's clinical requirements of Product for use in the United

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States, European Union, and any additional future jurisdictions as mutually agreed to by the Parties in writing.

3.6 <u>Commercial Supply Agreement</u>. Within [\*\*] days following the execution of this Agreement, the Parties shall negotiate in good faith and use commercially reasonable efforts to enter into a commercial manufacturing supply agreement for the commercial supply of Product, which agreement shall include the terms set forth in <u>Exhibit I</u> and other commercially reasonable terms mutually agreed to by the Parties ("Commercial Supply Agreement").

## 4. SUPPLY

- 4.1 <u>Initial Orders</u>. The Parties acknowledge that Customer has submitted, and Agilent has accepted, the initial Purchase Orders for Product attached hereto as Exhibit B (the "<u>Initial Orders</u>"). Customer may not make changes to or cancel the Initial Orders without Agilent's prior written consent.
- 4.2 <u>Forecasts</u>. Commencing on the Effective Date and every [\*\*] months thereafter, Customer shall submit to Agilent a written rolling forecast of the quantity of Product which Customer expects to order from Agilent over the next [\*\*] months ("<u>Forecast</u>"). The Forecast shall constitute a non-binding, good faith estimate provided by Customer solely to assist Agilent in production planning, and shall not represent any purchase commitment by Customer or a supply commitment by Agilent. It is understood and agreed by the Parties that Agilent will not hold inventory of Product. However, Agilent shall deliver such quantities of Product that are ordered in accordance with a binding Purchase Order that has been accepted by Agilent, provided that such Purchase Order is in accordance with the lead times set forth in Sections 4.3.1.

#### 4.3 <u>Future Orders.</u>

- 4.3.1 During the term of this Agreement, Customer may place Purchase Orders with Agilent. Each such Purchase Order shall be submitted by Customer (i) no later than [\*\*] months prior to the requested delivery date for large scale production (i.e., [\*\*] Kilos or greater) and (ii) no later than [\*\*] months prior to the requested delivery date for all other Purchase Orders. Customer may not increase the quantity of Product ordered under a Purchase Order without the prior written consent of Agilent. Notwithstanding the foregoing, Agilent shall use commercially reasonable efforts to fill an increased Purchase Order upon receiving Customer's written request therefor.
- 4.3.2 Acceptance of Purchase Orders. Agilent shall notify Customer as to whether any Purchase Order delivered pursuant to Section 4.3.1 has been accepted or rejected within [\*\*] business days following Agilent's receipt of such Purchase Order. Agilent may only reject a Purchase Order that (i) is not in compliance with this Agreement; (ii) does not have a delivery address; (iii) does not comply with Agilent's credit limit standards (consistent with Agilent's corporate policy); provided that if Customer agrees to make an up-front payment with respect to such Purchase Order, Agilent may not reject the Purchase Order on the basis that it does not comply with Agilent's credit limit standards; or (iv) does not comply with the lead times set forth in Section 4.3.1. Agilent's failure to affirmatively reject a Purchase Order within the [\*\*] business day period shall be deemed an acceptance of such Purchase Order. In the event that Agilent rejects a Purchase Order hereunder, Agilent shall notify Customer in writing within [\*\*] business days of the reasons why such Purchase Order was rejected by Agilent. Customer may, at its option, submit a revised Purchase Order.
- 4.3.3 <u>Details for Purchase Orders</u>. Each Purchase Order shall specify Product ordered and the time, manner and address of delivery, all of which shall be subject to this Article 4.

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- 4.3.4 Fulfillment of Purchase Orders. Agilent will use commercially reasonable efforts to complete the Manufacturing Services (including without limitation delivery of any Batch) by the timeframe estimated in the applicable Statement of Work and Purchase Order. Customer expressly acknowledges that delivery dates are approximate. Agilent's failure to complete the Manufacturing Services or deliver any Batch by any specified date will not be sufficient cause for cancellation of the Purchase Order by Customer, nor will Agilent be liable for any direct, indirect, consequential, or economic loss or damages due to delay in delivery. Notwithstanding the foregoing, in the event that Agilent (i) fails to complete the Manufacturing Services or deliver a Batch by the date specified in the applicable Statement of Work and Purchase Order and (ii) fails to use commercially reasonable efforts to promptly complete the Manufacturing Services or deliver a Batch after such date, Customer shall have the right to cancel such Statement of Work or Purchase Order.
- 4.4 <u>Delivery and Acceptance</u>. Subject to Section 8.2.2, Agilent will deliver the Product to the carrier selected by Customer. Shipment terms are FCA Agilent's Dock Boulder (Incoterms 2010). Title and risk of loss will pass to Customer when the Product is delivered to Customer's carrier. Customer is responsible for payment of all shipment costs, including any insurance necessary to guard against loss or damage during shipment. Acceptance shall occur upon delivery of the Product to Customer's carrier.
- 4.5 <u>Certificates</u>. An appropriate Certificate of Analysis (which shall include a material safety data sheet) and Certificate of Compliance shall be provided with the shipment of each Batch delivered to Customer.
- 4.6 <u>Shipping Instructions</u>. Customer will provide Agilent with packaging and shipping instructions including temperature requirements, temperature monitoring instructions and packaging specifications. Notwithstanding any other provision of this Agreement, Agilent will not be liable for any loss or damage caused by Agilent's compliance with Customer's packaging and shipping instructions or any loss or damage caused by Customer's carrier.

# 5. **PROCESSING OF PRODUCT**

- 5.1 <u>Storage and Handling.</u> Agilent shall store and handle the raw materials and packaging components under appropriate conditions and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of such materials and components. Agilent shall store and handle the Product in accordance with the Specification and under appropriate conditions as defined by Customer in accordance with the Product stability studies and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of the Product.
- 5.2 <u>Manufacturing Standards</u>. Agilent shall manufacture the Product in conformity with the Process, Master Batch Record, GMP and the Specification (the "<u>Manufacturing Standards</u>").
- 5.3 Shortage of Supply. Agilent shall notify Customer immediately upon becoming aware of an event of force majeure under Article 12 or any other event that would render Agilent unable to supply any quantity of the Product required to be supplied hereunder. In such event, Agilent shall use commercially reasonable efforts to remedy such shortage, including allocating a pro-rata portion of any available materials or prioritizing capacity based on the production of the Product for Customer and the production of products for Agilent's other customers according to the relative quantities ordered during the immediately preceding [\*\*] months prior to such shortage; provided, however, that Customer shall receive treatment proportionately no less

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 $favorable\ than\ any\ of\ Agilent's\ other\ customers\ with\ respect\ to\ allocation\ of\ such\ materials\ or\ prioritization\ of\ capacity.$ 

5.4 <u>Safety Stock</u>. Except with respect to the supply of PEG, Agilent shall at its own risk and expense, maintain a supply of raw materials and components necessary for the manufacture of Product based on accepted Purchase Orders.

- 5.5 Alternative Supplier. Agilent acknowledges that (i) it is the intent of Customer to establish an alternative supplier to manufacture Product and (ii) in the process of establishing such an alternative supplier Customer will discuss the Product and Customer's Know-How, subject to Article 14. Customer shall be free to disclose to any such actual or proposed alternative supplier the Process overview set forth in Exhibit H.
- Process Changes. Agilent agrees that no change to the Process shall be made without the prior written approval of Customer.

  Notwithstanding the foregoing, any such change to the Process shall be subject to the agreed upon Change Management process as set forth in the Quality Agreement and the prior mutual agreement of the Parties with respect to the costs and expenses associated with the agreed upon change.

# 6. PRICE AND PAYMENT

- 6.1 Pricing. Pricing for the Product shall be as set forth in each Statement of Work; provided that such pricing shall not exceed the pricing for Product set forth in Exhibit J except to the extent that the Manufacturing Standards as of the Effective Date for Product ordered are materially modified pursuant to the Change Management provisions set forth in the Quality Agreement; provided that any increase in pricing shall be proportionate to the increase in Agilent's costs to manufacture Product based on such modified Manufacturing Standards.
- 6.2 <u>Payment</u>. Agilent shall invoice Customer at the time of, as applicable, shipment of the Product in accordance with this Agreement or completion of the Manufacturing Services, unless otherwise agreed to by the Parties in a Statement of Work. Payment of an invoice for Product is due [\*\*] days from the date of Customer's receipt of invoice.
- 6.3 Taxes. Prices are exclusive of any sales, use, service, value added or other taxes. Any tax, duty, custom, insurance or other fee of any nature imposed on Product or services by any federal, state, local or foreign governmental authority shall be paid by Customer. If Agilent is required to pay any such tax or fee, Customer will reimburse Agilent promptly upon invoice by Agilent. If Customer claims exemption from any taxes, Customer will provide Agilent with an appropriate exemption certificate for the delivery jurisdiction.
- 6.4 Remedies. Agilent may temporarily discontinue its performance of the manufacture and supply obligations under this Agreement if Customer fails to pay any sum when due and Customer has not cured such failure within [\*\*] business days after receipt of written notice from Agilent identifying such failure.

## 7. WARRANTIES

7.1 <u>General Warranties</u>. Each Party warrants to the other Party that (i) it has the right and authority to enter into this Agreement and to carry out its obligations hereunder; (ii) it is validly existing in each jurisdiction in which it is incorporated and is authorized to do business under the laws of each jurisdiction in which it engages in business activities; and (iii) it is not aware of any legal,

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contractual or other restriction, limitation or condition that might adversely affect its ability to perform its obligations hereunder.

- 7.2 Warranties by Agilent. Notwithstanding any prior acceptance of Product by Customer in accordance with Section 4.4 Agilent warrants to Customer that (i) all Product supplied under this Agreement shall conform to the Specification at the time of delivery to Customer's carrier; and (ii) all Product delivered hereunder shall be delivered to Customer free and clear of all liens and security interests.
- 7.3 <u>Warranties by Customer</u>. Customer warrants to Agilent that (i) it owns or has the necessary rights, title and interest in and to the Product, including the right under Patents owned or controlled by Customer to have Product made for Customer, and (ii) as of the Effective Date, Customer has not received any written notification alleging that the Product infringes the intellectual property rights of any Third Party.
- 7.4 Remedies. In the event that the Product supplied under this Agreement did not conform to the Specification at the time of delivery to Customer's carrier, or the Product delivered to Customer was not free and clear of all liens and security interests, Customer shall have the remedies set forth in Section 8.2.3.6.
- 7.5 <u>No Warranty to Third Parties</u>. The warranties set forth in Section 7.2 are solely for the benefit of Customer. Agilent makes no warranty to Customer's end-user customers or any other Third Party. Customer will not pass on to any end-user customer or any other Third Party any warranty or representation on behalf of Agilent.
- 7.6 <u>DISCLAIMER</u>. THE ABOVE WARRANTIES ARE EXCLUSIVE AND EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES NOR RECEIVES ANY WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF DESIGN, SUITABILITY OF QUALITY, OR ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE PRACTICE, WITH REGARD TO THE PRODUCT. AGILENT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.

## 8. **QUALITY**

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

## 8.2 **Quality Assurance.**

8.2.1 <u>Testing by Agilent</u>. Agilent shall perform quality testing using assays, including assays developed under a Statement of Work, mutually agreed to by the Parties in order to assure that Product complies with the Specification as set forth in the applicable Statement of Work, and shall retain samples of Product as required by applicable law and produce records of the tests made on

of Work. In addition, no Product shall be delivered until such Product has been Processed in

accordance with the agreed upon testing specifications; provided, however, that the foregoing shall not relieve Agilent of its obligation under this Section 8.2.

each Batch. Agilent shall provide Customer a Certificate of Analysis and Certificate of Compliance confirming the performance of such testing. Customer may elect, at its sole discretion, to attend and observe any testing conducted by Agilent in accordance with this Section 8.2.1. The Parties agree that the initial testing specifications for Product are as set forth in the related Statement

- 8.2.2 Records. Agilent shall maintain records, including Master and Batch Production Records, with respect to the manufacturing and quality testing of the Product and shall deliver the Executed Batch Record to Customer electronically prior to shipment of the associated Batch of Product. Agilent shall not ship Product hereunder unless and until: (i) Agilent has provided to Customer the Executed Batch Record for such Product and under the condition that all opened deviations, investigations or other anomalous events related to such Batch have been resolved, and (ii) Customer has reviewed the Executed Batch Record for such shipment and authorized such shipment in writing. Agilent shall promptly respond to any questions or requests for additional information that Customer may have with respect to such Executed Batch Record. Notwithstanding the foregoing, in the event that (a) Customer fails to provide such authorization within [\*\*] business days after Customer's receipt of the Executed Batch Record and (b) Customer has not within such [\*\*] business day period submitted to Agilent any questions or requests for information and (c) Customer does not within such [\*\*] business day period find fault or anomaly with the balance of the Batch Packet documentation, then Agilent may ship the associated Batch of Product and Customer shall be deemed to have accepted the Executed Batch Record. Agilent shall provide Customer with the remaining Batch Packet documentation (i.e., the records and documentation identified in Sections 2.1.6.2 through 2.1.6.7 of the Quality Agreement) at least [\*\*] business days prior to the proposed Product shipment date. Such records shall also be made available to Customer during normal business hours, upon prior written request.
- 8.2.3 <u>Non-Conforming Product</u>. Notwithstanding any prior acceptance of Product or the Batch Packet by Customer in accordance with Sections 4.4 or 8.2.2, the following shall apply with respect to non-conforming Product:
  - 8.2.3.1 <u>Inspection/Testing</u>. Upon receipt of each delivery of Product from Agilent under this Agreement, Customer shall report to Agilent within [\*\*] business days of Customer's receipt of Product if the Product does not conform to the quantity specified in the Purchase Order, or if the Product is otherwise not in Good Condition.
  - 8.2.3.2 Failure to Conform to the Quantity; Good Condition. In the event Customer notifies Agilent pursuant to Section 8.2.3.1 that the quantity of Product delivered does not conform to the quantity specified in the Purchase Order, Agilent shall deliver, at Agilent's expense, such additional quantity of Product as is necessary to meet the quantity specified in the Purchase Order as soon as reasonably practicable. In the event Customer notifies Agilent pursuant to Section 8.2.3.1 that the Product is not in Good Condition at the time of delivery, Agilent shall have the right to inspect and analyze the Product. In the event that the Parties agree that the Product was not in Good Condition at the time of delivery, Customer shall have the remedies as set forth in Section 8.2.3.6. If the Parties cannot agree as to whether the Product was in Good Condition at the time of delivery, the matter shall be escalated in accordance with Section 16.b, Escalated Dispute Resolution.

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- 8.2.3.3 <u>Latent Defect</u>. In the event Customer discovers that the Product has a Latent Defect, Customer shall promptly notify Agilent in writing providing specific details about the nature of the Latent Defect.
- 8.2.3.4 Notification from Customer. In the event Customer notifies Agilent pursuant to Section 8.2.3.3 that the Product has a Latent Defect, (i) Agilent shall have the right to inspect and analyze the Product and (ii) the Parties shall work together in good faith to reach agreement as to whether the Product has a Latent Defect. In the event the Parties agree that the Product has a Latent Defect, Customer shall have the remedies as set forth in Section 8.2.3.6.
- 8.2.3.5 Independent Laboratory. In the event the Parties fail to agree whether the Product has a Latent Defect, the matter shall be referred to an Independent Laboratory. Agilent shall forward a sample of retained Product from the Batch in question to the Independent Laboratory for testing and control purposes. The Parties shall mutually agree to the controls and procedures used by the Independent Laboratory to test the Product. Agilent shall have the right to audit the Independent Laboratory to determine whether there was any departure from the established controls and procedures used to test the Product. In the event Agilent determines that there was a departure from the established controls and procedures, Agilent shall notify Customer in writing within [\*\*] business days and the Parties shall resolve the matter in accordance with Section 16.b. In the absence of such determination by Agilent, the decision of the Independent Laboratory shall be final and binding on the Parties. If the Independent Laboratory determines that the Product has a Latent Defect, then the Independent Laboratory's fees shall be borne by Agilent. If the Independent Laboratory determines that the Product does not have a Latent Defect, then Customer shall bear the Independent Laboratory's fees and reimburse Agilent for any reasonable direct costs incurred by Agilent in connection with the Independent Laboratory's analysis of the Product.
- 8.2.3.6 <u>Customer's Remedies</u>. The following remedies shall be available to Customer in the event the Product was not in Good Condition at the time of delivery to Customer's carrier or that the Product has a Latent Defect:
  - 8.2.3.6.1 Agilent may elect either to collect and dispose of the affected Product, at Agilent's expense, or to reimburse Customer for any reasonable costs incurred by Customer to collect and dispose of the affected Product;

- 8.2.3.6.2 Agilent shall reimburse Customer for all reasonable costs incurred by Customer in connection with delivery of the affected Product, including freight, clearance, duty and storage charges incurred by Customer; and
- 8.2.3.6.3 Agilent shall promptly, at no additional cost to Customer (subject to Section 15.3), (i) replace the affected Product as soon as reasonably practicable with Product that meets the requirements of Section 3.1 or (ii) rework the affected Product, subject to mutual agreement of the Parties. In the event that Agilent fails to replace the affected

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Product within the timeframe mutually agreed to by the Parties, Agilent will refund to Customer any amounts paid for such Product.

- 8.2.4 <u>Audit Rights</u>. Customer shall have the right to conduct audits and inspections of the Facility, Agilent's manufacturing operations and Agilent's records relating to this Agreement as provided in the Quality Agreement. Agilent shall reasonably cooperate with Customer in conducting such audits and inspections.
- 8.2.5 Observation by Customer. During the Term, Customer shall have the right, at Customer's sole cost and expense, during normal business hours and upon reasonable notice, to visit the Facility in order to ensure that the Processing complies with applicable legal requirements and the Specification, as applicable. Agilent shall reasonably cooperate with Customer to permit Customer such access in connection with such visits. At all times while in attendance at the Facility, Customer agrees to comply with all Agilent health and safety protocols and other policies and procedures applicable to visitation of the Facility as notified by Agilent to Customer prior to or during such attendance. Such visits shall not interfere with Agilent's operations.
- 8.2.6 Recalls and Voluntary Withdrawals. If either Party becomes aware of information about the Product or Finished Product indicating that it may be non-conforming Product or that there is potential adulteration, misbranding and/or any potential issues regarding the safety or effectiveness of the Product or Finished Product, it shall within [\*\*] hours provide notice to that effect to the other Party. Customer will initiate an investigation and assessment of such circumstances and shall promptly notify Agilent of its findings and any proposed course of action. The Parties shall meet to discuss such circumstances and to consider appropriate courses of action. Customer shall bear all costs associated with a recall of the Product or Finished Product unless such recall is caused by Agilent's gross negligence or willful misconduct or the failure of Product to conform to the Specification or GMP requirements at the time of delivery to Customer's carrier, in which case Agilent shall pay all costs associated with the recall, subject to Article 15.

#### 9. **INTELLECTUAL PROPERTY**

- 9.1 <u>Background Property</u>. Each Party retains all right, title and interest in and to all Intellectual Property owned, licensed or developed by or on behalf of such Party prior to the Effective Date or independent of this Agreement, and without reliance on the other Party's Proprietary Information.
- 9.2 Ownership of Developed Intellectual Property.
  - 9.2.1 Customer shall be the sole owner of all right, title and interest in and to all Intellectual Property relating specifically to the Product, including the Specification and all improvements to the Product and Specification that are (i) jointly developed by Customer or its employees or consultants on the one hand and Agilent or its employees or consultants on the other hand, during the course of performing or receiving services hereunder or (ii) developed by Agilent or its employees or consultants during the course of performing Manufacturing Services under a Statement of Work or during the course of performing services for Customer under any Purchase Order, including the Initial Orders, ((i) and (ii) collectively, "Product Improvements"). Agilent hereby assigns to Customer all of its right, title and interest in Product Improvements. Agilent agrees to execute such assignments and other documents and to take such other actions as may be reasonably requested by Customer from time to time, at Customer's expense, in order to effect the ownership provisions of this Section 9.2.1. For avoidance of doubt,

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intellectual property relating to the Processing of nucleic acids and the Processing of modified nucleic acids, including pegylated nucleic acids, which is not sequence or Product specific shall not be considered to be a "Product Improvement" but shall be considered to be Intellectual Property relating to the Process, as provided in Section 9.2.2 below and not subject to the obligation to assign provided in this Section 9.2.1.

9.2.2 Agilent shall be the sole owner of all right, title and interest in and to all Intellectual Property relating to the Process, including all improvements thereto, that are developed by Agilent or its employees or consultants. In addition, Agilent shall be the sole owner of all right, title and interest in and to all Intellectual Property relating to the Process, including all improvements thereto, that are jointly developed by Customer or its employees or consultants and Agilent or its employees or consultants, during the course of performing or receiving services hereunder ("Joint Process Improvements"). Customer hereby assigns to Agilent all of its right, title and interest in Joint Process Improvements, except as otherwise provided in Section 9.3.2.1 below. Customer agrees to execute such assignments and other documents and to take such other actions as may be reasonably requested by Agilent from time to time, at Agilent's expense, in order to effect the ownership provisions of this Section 9.2.2.

# 9.3 License Grants.

9.3.1 License to Agilent.

9.3.1.1 During the Term, Customer hereby grants to Agilent a fully paid, non-exclusive, non-sublicensable (except as otherwise permitted under Section 9.5), non-transferable (except to a permitted assignee in accordance with Section 16(e) ("Permitted Assignee")) license under any and all Customer Intellectual Property that is necessary for Agilent to perform its obligations under this Agreement, for the sole and limited purpose of Agilent's performing its obligations under this Agreement.

## 9.3.2 <u>Licenses to Customer</u>.

Agilent hereby grants to Customer a worldwide, fully paid-up, royalty-free, perpetual, non-sublicensable (except in accordance with this Section 9.3.2.1), non-transferable and non-assignable (except to a Permitted Assignee), (x) non-exclusive license under Joint Process Improvements; and (y) non-exclusive license under analytical methods that are developed by Agilent in the performance of a Statement of Work (including Statements of Work dated prior to the Effective Date that are identified in Exhibit E) or a Purchase Order, including the Initial Orders, ("Analytical Methods") (together with Joint Process Improvements, collectively, "Licensed Technology") to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, import, and have imported the Product and Finished Product, subject to the following: (i) any sublicense granted by Customer to a Third Party manufacturer or a Third Party that Customer has granted a license under Customer Intellectual Property to clinically develop Product ("Customer Licensee") and/or Finished Product shall be restricted to using the Licensed Technology for the sole purpose of performing services (including development and manufacturing services) for the Product or Finished Product exclusively for Customer, Customer's Affiliates, Customer Licensees or a Permitted Assignee and (ii) prior to disclosing any Licensed Technology to any Third Party, Customer shall enter into a valid written confidentiality agreement with such Third Party that (a) requires the

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Third Party to maintain the confidentiality of Agilent Proprietary Information contained in the Licensed Technology under terms no less restrictive than those set forth in Article 14 of this Agreement and (b) restricts the Third Party from using the Licensed Technology for any purpose other than to perform services for the Product or Finished Product exclusively for Customer, Customer's Affiliates, Customer Licensees or a Permitted Assignee in accordance with this Section 9.3.2.1. In addition, any sublicense to Analytical Methods granted by Customer under this Section 9.3.2.1 to a Third Party manufacturer of Finished Product shall be restricted to those Analytical Methods that are necessary to manufacture and release the Finished Product. In addition to the non-exclusive license granted above, and solely with respect to Joint Process Improvements, Agilent hereby grants to Customer a worldwide, fully paid-up, royalty-free, perpetual, non-sublicensable (except in accordance with this Section 9.3.2.1), non-transferable and non-assignable (except to a Permitted Assignee) license to use Joint Process Improvements on a non-exclusive basis to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, import, and have imported products controlled by Customer, provided that (i) any sublicense granted by Customer to a Third Party manufacturer or a Customer Licensee shall be restricted to using the Joint Process Improvements for the sole purpose of performing services (including development and manufacturing services) exclusively for Customer, Customer's Affiliates, Customer Licensees or a Permitted Assignee and (ii) prior to disclosing any Joint Process Improvements to any Third Party, Customer shall enter into a valid written confidentiality agreement with such Third Party that (a) requires the Third Party to maintain the confidentiality of Agilent Proprietary Information contained in the Joint Process Improvements under terms no less restrictive than those set forth in Article 14 of this Agreement and (b) restricts the Third Party from using the Joint Process Improvements for any purpose other than to perform services exclusively for Customer, Customer's Affiliates, Customer Licensees or a Permitted Assignee in accordance with this Section 9.3.2.1. Except as expressly provided herein, no license to any Licensed Technology is granted, conveyed or implied. [\*\*].

- 9.3.2.2 Agilent hereby grants to Customer a non-exclusive, royalty-free, non-sublicensable (except in accordance with this Section 9.3.2.2), non-transferable and non-assignable (except to a Permitted Assignee) license, under the Licensed Patents, to make, have made, use, import, offer for sale and sell the Product and Finished Product, subject to the following: any sublicense granted by Customer to a Third Party manufacturer or Customer Licensee shall be restricted to developing and manufacturing the Product or Finished Product exclusively for Customer, Customer's Affiliates, Customer Licensees or a Permitted Assignee and shall contain a provision identifying Agilent as an intended third party beneficiary of, and entitled to enforce, any such sublicense. No other license is granted by Agilent under this Agreement, either directly or by implication, under any Patent other than the Licensed Patents. [\*\*].
- 9.3.2.3 Upon the written request of Customer and provided that the Commercial Supply Agreement is in effect between the Parties, Agilent hereby grants to Customer a non-exclusive, royalty-bearing, non-sublicensable (except to a Third Party manufacturer or Customer Licensee in accordance with this Section 9.3.2.3), non-transferable and non-assignable (except to a Permitted Assignee) license,[\*\*]. In the event that Customer exercises its right to such a license: (i)

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- [\*\*] of this Agreement, [\*\*], and [\*\*]; and [\*\*]. In addition, [\*\*] under this Section 9.3.2.3 [\*\*] with this Section 9.3.2.3 shall not be deemed a material breach of this Agreement and Agilent shall not have the right to terminate this Agreement as a result of such disclosure under Section 13.2(a) or 13.2(c), provided that Customer has complied with the terms set forth in this Section 9.3.2.3.
- 9.3.2.4 Customer shall not disclose any Agilent Know-How, or any Third Party Know-How disclosed to Customer under the Confidentiality Agreement, to any Third Party without obtaining Agilent's express prior written consent to such

disclosure. [\*\*].

- 9.3.2.5 Notwithstanding any other provision herein, Customer shall not [\*\*] shall not be unreasonably withheld or delayed. In the event that Customer is [\*\*].
- 9.4 <u>Reservation of Rights</u>. Except as expressly provided herein, no license to any Agilent Intellectual Property or Customer Intellectual Property is granted, conveyed or implied. For the avoidance of doubt, no license to any Agilent Know-How owned, licensed or developed by or on behalf of Agilent is granted, conveyed or implied except pursuant to the license granted to Customer under Section 9.3.2.3. All rights not conferred are expressly reserved.
- 9.5 <u>Subcontracting.</u> Agilent shall only engage those Affiliates and Third Parties approved by Customer in writing to manufacture the Product and shall not sub-license the rights under any Customer Intellectual Property other than to such approved Affiliates and Third Parties and solely for the purpose of manufacturing and supplying Product to Customer.
- 9.6 <u>Disclosure of Process Patents, Process Overview and Know-How.</u>
  - 9.6.1 <u>Disclosure of Process Patents</u>. All Patents owned or licensed by Agilent that cover or claim the Process are set forth in Exhibit F. During the Term, upon the reasonable request of Customer, no more than [\*\*], Agilent shall update Exhibit F. Agilent shall not incorporate into the Process any Patents unless the Parties have agreed to incorporate such Patents into the Process pursuant to the Change Management process.
  - 9.6.2 <u>Disclosure of Process Overview</u>. An overview of the Process is attached to this Agreement as Exhibit H. Agilent acknowledges and agrees that Exhibit H does not contain any Agilent Proprietary Information and that Customer may disclose Exhibit H, or any information contained therein, to any Third Party to the extent such Third Party has a reasonable need to know such information.
  - 9.6.3 Third Party Know-How. Agilent has not and shall not incorporate into the Process any Third Party Know-How unless (A) Agilent has the right to sublicense such Third Party Know-How to Customer in accordance with Section 9.3.2.3 and (B) the Parties have agreed to incorporate such Third Party Know-How into the Process pursuant to the Change Management process. In addition, Agilent shall not disclose to Customer any Third Party Know-How unless (A) Agilent has the right to sublicense such Third Party Know-How to Customer in accordance with Section 9.3.2.3 and (B) prior to such disclosure, Agilent notifies Customer that such Know-How is Third Party Know-How. In the event that the Parties agree to incorporate Third Party Know-How into the Process under this Section 9.6.3, any license granted to Customer under Section 9.3.2.3 shall include such Third Party Know-How.
- 9.7 <u>Licenses to Use the Process</u>. Agilent is responsible for the procurement of any licenses to Intellectual Property necessary to use the Process to manufacture the Product under this Agreement. Agilent shall have full responsibility for the determination of whether and from

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which Third Party it requires any such license to Intellectual Property claiming or covering the Process for the manufacture of the Product under this Agreement and for the procurement of any such license. For purposes of clarity, nothing in this Section 9.7 shall limit or prevent Customer, in its sole discretion, from obtaining any license or other rights to any Third Party Intellectual Property necessary or useful to manufacture the Product.

9.8 Third Party Infringement Claims. Agilent will defend or settle any Third Party claim against Customer, its officers, directors and employees, that Agilent's use of the Process to manufacture the Product under this Agreement infringes the Third Party's Intellectual Property rights. The Parties shall comply with the indemnification process set forth in Section 10.3 with respect to any such Third Party claims. Agilent will pay infringement defense costs, settlement amounts and court awarded damages. Agilent shall have no obligation under this Section 9.8 for any claim of infringement arising from Product use prohibited by this Agreement. This Section 9.8 states Customer's sole and exclusive remedy with respect to any such Third Party claim.

# 10. INDEMNITIES AND INSURANCE

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

  Customer's obligations under this Section 10.2 do not apply with respect to any claim subject to indemnification under Section 10.1.
- Process. Each Party agrees to notify the other Party promptly upon receipt of any claim for which indemnification is sought. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. In no event may either Party compromise or settle any claim or suit in a manner that admits fault or negligence on the part of the other Party (or any indemnitee) without the prior written consent of the other Party, which consent shall not be unreasonably withheld. The indemnifying party shall have no liability under this Article 10 with respect to claims or suits settled or compromised by the indemnified party without the indemnifying party's prior written consent. The indemnified Party may, at its own expense, participate in the defense of any claim. In the event that the indemnifying Party fails to assume control of the defense of any claim, the indemnified Party may assume control at the expense of the indemnifying Party.

10.4 <u>Insurance</u>. During the term of this Agreement, Agilent will maintain insurance coverage in accordance with the Memorandum of Insurance attached hereto as Exhibit D.

#### 11. COMPLIANCE WITH LAWS AND REGULATORY MATTERS

11.1 <u>Compliance with Laws</u>. Each Party shall comply with all applicable laws and regulations governing the performance of such Party's obligations under this Agreement. Without limiting

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the foregoing, Agilent shall ensure that the Facility conforms to GMP and the requirements of all applicable Regulatory Authorities.

- 11.2 <u>Regulatory Filings</u>. Customer, at its expense, shall be solely responsible for the preparation, filing and maintenance of all regulatory documents and all governmental permits, licenses and other approvals as may be necessary with respect to the formulation, marketing, distribution sale and use of the Product and Finished Product. Upon Agilent's request, Customer will provide Agilent with a copy of all regulatory documents relating to the manufacture of Product under this Agreement.
- 11.3 <u>Use Restrictions.</u> Notwithstanding any other provision of this Agreement, Customer acknowledges and agrees that the Product manufactured by Agilent and supplied to Customer under this Agreement (i) is not intended for commercial use and (ii) shall not be used for commercial purposes. For avoidance of doubt, validation Batches shall be manufactured and supplied to Customer under the Commercial Supply Agreement.
- 11.4 <u>Permits.</u> Agilent at its expense shall be solely responsible for, and has the obligation to prepare, file and maintain all licenses, permits and approvals as may be necessary with respect to the manufacture of the Product at the Facility, including all regulatory approvals required to import raw materials and packaging components.
- 11.5 <u>Export Controls.</u> Each Party shall comply with applicable US and other laws, rules and regulations that govern the import, export and reexport of the Product, including the U.S. Export Administration Regulations, and will obtain any required export and import authorizations.
- 11.6 Record Retention. Agilent shall maintain the records and documentation relating to the manufacture of the Product in accordance with ICH guidance, Agilent's Standard Operating Procedure and the Quality Agreement.

## 11.7 <u>Technical Support</u>.

- 11.7.1 Upon notification to Agilent that Customer has received a complaint or inquiry regarding the safety, efficacy or quality of the Product or Finished Product, Agilent shall, within a reasonable period, supply Customer with a chemical analysis of a number of retained samples, maintained in accordance with the Quality Agreement, of the Batch(es) of the Product in question.
- 11.7.2 Upon notification to Customer that Agilent has received a complaint or inquiry regarding or discovery by Customer of any issues relating to the safety, efficacy or quality of the Product or Finished Product, Customer shall, within a reasonable period, provide technical support as reasonably requested by Agilent, which may include, but shall not be limited to, technical advice and chemical analysis of retained samples of the Product, maintained in accordance with the Quality Agreement.
- 11.7.3 All technical support provided by Agilent under this Section 11.7 shall subject to the pricing and payment terms for technical and regulatory support as set forth in the Statement of Work.

# 11.8 <u>Regulatory Support.</u>

11.8.1 Agilent agrees to cooperate with, and provide regulatory assistance to, Customer to support existing, pending or new Product or Finished Product registrations and marketing approvals, in each case, with any relevant governmental authority. The foregoing assistance rendered by Agilent may include: (i) assisting Customer in completing and submitting changes to any regulatory submissions related to the Product; (ii) cooperation in connection with pre-approval inspections carried out by governmental

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authorities; and (iii) providing information to Customer that may be required by a relevant governmental authority to support the Product or Finished Product, including the manufacturing and exportation related thereto. All regulatory support provided by Agilent under this Section 11.8 shall be subject to the pricing and payment terms for technical and regulatory support as set forth in the Statement of Work.

11.9 FDA Debarment Statement. Agilent hereby certifies that neither Agilent nor any employee engaged by Agilent to perform services under this Agreement has been debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with the performance of services under this Agreement or any comparable law or regulation outside of the United States. In the event that Agilent becomes aware of any such debarment, Agilent will provide Customer with written notice thereof. Agilent will request that all GMP manufacturing and testing subcontractors utilized pursuant to Section 2.4 of the Quality Agreement provide Customer with a certification that is substantially similar to the certification provided by Agilent in this Section 11.9. In the event that any such subcontractor fails to provide the certification, Customer may withdraw its approval for such subcontractor and Agilent shall cease using such subcontractor to provide services under this Agreement.

#### 12. FORCE MAJEURE

Neither Party will be liable for any failure or delay in performance of its obligations under this Agreement to the extent such failure or delay is caused by any event beyond such Party's reasonable control, including fire, flood, explosion, unavailability of utilities or raw materials, labor difficulties, war, riot, act of God, export control regulation, or other laws or regulations, action or failure to act of any governmental authority, or any judgment, injunction or order of a court, administrative agency or regulatory authority having the effect of preventing or adversely affecting either Party's performance under this Agreement.

## 13. TERM AND TERMINATION

13.1 <u>Term.</u> Unless otherwise terminated under this <u>Article 13</u>, this Agreement will commence as of the Effective Date and will continue for five (5) years (the "<u>Initial Term</u>"). Unless otherwise terminated in accordance with this Article 13, this Agreement shall be automatically extended for an indefinite period (the "<u>Renewal Term</u>" and together with the Initial Term, the "Term"). Notwithstanding any of the foregoing, either Party may terminate this Agreement at the end of the Initial Term or during the Renewal Term provided, however, that it has given the other Party at least eighteen (18) months prior written notice of termination.

## 13.2 <u>Termination</u>.

- (a) This Agreement or a Statement of Work may be terminated by either Party upon [\*\*] days written notice in the event of a material breach of any provision of this Agreement or such Statement of Work; provided, however, that the breaching Party will have an opportunity to (i) cure the breach during the [\*\*], or (ii) provide the non-breaching Party with a plan to remedy the breach within the [\*\*], and if so cured, no termination will be deemed to have occurred as long as the breaching Party diligently pursues the plan to remedy the breach and completes such plan in accordance with the time frame mutually agreed to by the Parties (such time frame not to exceed an additional [\*\*] days); or
- (b) This Agreement may be terminated by either Party immediately upon written notice to the other Party (i) if the other Party makes an assignment for the benefit of creditors; (ii) if proceedings in voluntary or involuntary bankruptcy are initiated by, on behalf of or against the other Party (and, in the case of any such involuntary proceeding, not dismissed within ninety (90) days); (iii) if the other Party is adjudicated bankrupt, files a petition under insolvency laws, is dissolved or has a receiver appointed for substantially all of its property; or (iv) if the other Party

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ceases operation of its business as its business has normally been conducted, or terminates substantially all of its employees.

- (c) In the event of either Party's material breach of its confidentiality obligations under Article 14 with respect to trade secrets of the disclosing Party which have been specifically identified as such in writing by the disclosing Party, the Parties shall refer the matter for resolution under the escalated dispute resolution process set forth in Section 16(b). In the event that the Parties are unable to resolve the matter following the dispute resolution process set forth in Section 16(b), then the non-breaching Party may terminate this Agreement upon written notice to the breaching Party. For the avoidance of doubt, [\*\*].
- (d) This Agreement or a Statement of Work may be terminated by Customer, with or without cause, upon twelve (12) months prior written notice to Agilent.
- (e) In the event that Customer fails, under this Agreement or under the Commercial Supply Agreement, for a period of thirty-six (36) months (i) to place a Purchase Order for a minimum of one hundred (100) oligonucleotide grams of Product and (ii) to take delivery of such Product within the lead times as set forth in Section 4.3.1 of this Agreement or within the lead times as set forth in the Commercial Supply Agreement, Agilent shall have the right to terminate this Agreement upon written notice to Customer without further opportunity to cure.

# 13.3 <u>Effect of Termination or Expiration</u>.

- 13.3.1 Section 3.5.1 shall survive termination or expiration of this Agreement unless terminated by Agilent pursuant to Section 13.2(a), (b), (c) or (e), or by Customer pursuant to Section 13.1 or 13.2(d). If this Agreement is terminated by Customer pursuant to Section 13.2(a), (b) or (c), the obligations under Section 3.5.1 shall survive such termination for a period of five (5) years after the effective date of such termination, regardless of whether the Commercial Supply Agreement is in effect.
- 13.3.2 Termination or expiration of this Agreement or any SOW shall not release either Party from any liability, right of action or other obligation which has arisen prior to such termination or expiration including Agilent's obligation to deliver to Customer such quantity of Product under any accepted Purchase Order by Agilent prior to the effective date of termination or expiration, and Customer's obligation to pay Agilent the amount set forth in such Purchase Order. In addition, in the event of termination of any SOW under Section 13.2, Customer shall pay Agilent for all work performed under such SOW prior to the termination date.
- 13.4 <u>Surviving Provisions</u>. Notwithstanding any expiration or termination of this Agreement, the following provisions shall survive: 6.2, 6.3, 7, 8.2.3, 8.2.6, 9, 10, 11, 12, 13, 14, 15 and 16.

#### 14. CONFIDENTIAL INFORMATION

- Proprietary Information. The terms and conditions of Confidentiality Agreement dated March 22, 2011, by and between Customer and Agilent ("Confidentiality Agreement"), attached hereto as Exhibit G and incorporated herein by this reference. Capitalized terms used in this Article 14 and not defined in this Agreement shall have the meanings ascribed to them in the Confidentiality Agreement. The terms and conditions of the Confidentiality Agreement shall apply to information exchanged under this Agreement; provided that:
  - 14.1.1 with respect to information exchanged pursuant to this Agreement, the "Purposes" as defined in Section 1 of the Confidentiality Agreement shall be amended to mean the conduct of activities and exercise of rights granted pursuant to this Agreement;

- 14.1.2 notwithstanding Section 3 of the Confidentiality Agreement, the Confidentiality Agreement shall apply to all Proprietary Information disclosed between the Parties pursuant to the Confidentiality Agreement and/or this Agreement from March 22, 2011 until the end of the Term;
- 14.1.3 notwithstanding Section 8(c) of the Confidentiality Agreement, as it applies to information exchanged under this Agreement, shall be construed and interpreted in accordance with the laws of the State of New York as provided in Section 16(k);
- 14.1.4 notwithstanding Section 8(e) of the Confidentiality Agreement, the obligations of confidentiality and non-use under the Confidentiality Agreement shall apply until the [\*\*] anniversary of the expiration or termination of this Agreement;
- 14.1.5 the restrictions on disclosure and use set forth in the Confidentiality Agreement shall not apply to the disclosure of this Agreement or the disclosure of Proprietary Information to governmental authorities (i) that is required by applicable law or regulation to be submitted by Customer in connection with the issuance or maintenance of marketing approvals for the Product or Finished Product; (ii) that is submitted by either Party to comply with requests for information from any governmental authority; or (iii) that is submitted by either Party to comply with applicable governmental regulations (including the rules and regulations of any stock exchange); provided that, (x) to the extent permitted by applicable law, Customer or Agilent, as the case may be, will give reasonable advance notice to the other Party of such disclosure requirement in order to allow the other Party the opportunity to seek appropriate legal relief to prevent or limit disclosure of its Proprietary Information; (y) reasonable measures shall have been taken by the Party seeking to disclose the other Party's Proprietary Information to ensure confidential treatment of such Proprietary Information; and (z) any disclosure shall be limited to such portion of the other Party's Proprietary Information that is legally required to be disclosed.
- 14.1.6 notwithstanding anything to the contrary in the Confidentiality Agreement, but subject to Section 14.1.1, in the event that the Recipient wishes to disclose this Agreement or the Disclosing Party's Proprietary Information to actual or potential investors, lenders, acquirers, merger partners, or professional advisors who have a reasonable need to know such information, the Recipient shall provide prior written notice thereof to the Disclosing Party, and the Parties shall promptly meet (in person or via telephone) and confer prior to any such disclosure for the purpose of avoiding any inappropriate disclosure of the Disclosing Party's Proprietary Information. Following such meeting, if the Disclosing Party has provided its express prior written consent to such disclosure, which consent shall not be unreasonably withheld or delayed, the Recipient may disclose the Disclosing Party's Proprietary Information to such Third Party; provided that (i) the Recipient shall only disclose such amount of the Disclosing Party's Proprietary Information as is reasonably necessary; and (ii) the Recipient has entered into a confidentiality agreement, with terms of confidentiality at least as restrictive as the terms and conditions set forth in this Article 14 and the Confidentiality Agreement, with such Third Party (other than attorneys and accountants of Recipient who are bound to confidentiality under applicable ethical and professional rules) before disclosing any of the Disclosing Party's Proprietary Information. In the event that the Disclosing Party has not consented to such disclosure, the Recipient may engage an independent Third Party consultant reasonably acceptable to the Disclosing Party and subject to confidentiality obligations at least as restrictive as the terms and conditions set forth in this Article 14 and the Confidentiality Agreement, to evaluate the Parties' rights and obligations hereunder and such independent Third Party consultant shall be permitted to

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disclose to such Third Party confirmation solely regarding the adequacy of such rights and obligations and the performance hereunder. For the avoidance of doubt, the independent Third Party consultant shall not be permitted to disclose any Proprietary Information of the Disclosing Party to any Third Party. The Parties agree that the process set forth in this Section 14.1.6 shall not apply to Customer's use or exercise of the license rights under Sections 9.3.2.1, 9.3.2.2 or 9.3.2.3, provided that Customer complies with the provisions of the applicable Sections 9.3.2.1, 9.3.2.2 or 9.3.2.3. In addition, in the event that Customer exercises the license rights under Section 9.3.2.3, the Parties further agree that the process set forth in this Section 14.1.6 shall continue to apply prior to disclosure of this Agreement or any Proprietary Information to any actual or potential investor, lender, acquirer, merger partner or professional advisor.

Remedies. Each Party shall be entitled, in addition to any other right or remedy it may have, at law, in equity or under this Agreement, to seek temporary, preliminary and permanent injunctions, enjoining or restraining the other Party and its Affiliates from any violation or threatened violation of this Article 14.

## 15. **LIMITATION OF LIABILITY**

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

PERMITTED BY LAW, AGILENT'S LIABILITY TO CUSTOMER UNDER THIS AGREEMENT IS LIMITED TO THE AGGREGATE AMOUNTS PAID BY CUSTOMER TO AGILENT IN RESPECT OF THE RELEVANT BATCH FROM WHICH THE CLAIM AROSE.

15.3 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL AGILENT BE LIABLE FOR ANY COSTS WHATSOEVER TO PROCURE, SUPPLY OR REPLACE PEG, REGARDLESS OF WHETHER SUCH COSTS ARE BASED ON TORT, CONTRACT, WARRANTY, LATENT DEFECT, INDEMNITY OBLIGATIONS OR ANY OTHER LEGAL THEORY, EXCEPT TO THE EXTENT THAT SUCH COSTS ARE SOLELY AND DIRECTLY CAUSED BY AGILENT'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

#### 16. MISCELLANEOUS

a. <u>Notices</u>. All notices required or permitted to be given under this Agreement must be in writing and delivered to the other Party as set forth below. Notices are validly given upon the earlier of confirmed receipt by the receiving Party or three (3) days after dispatch by a reputable courier or

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certified mail, return receipt requested. Either Party may change its designated contact and address for purposes of notice by giving notice to the other Party in accordance with these provisions.

Agilent Technologies, Inc.

Ophthotech Corporation
214 Carnegie Center

Suite 100 Suite 302

Boulder, CO 80301 Princeton, NJ 08540
Attn: General Manager Attn: Chief Business Officer

With a copy to:

Agilent Technologies, Inc.

5301 Stevens Creek Blvd.

Santa Clara CA 95051

Attn: General Counsel

Ophthotech Corporation
One Penn Center, 19th Floor
New York, NY 10119
Attn: General Counsel

- b. <u>Escalated Dispute Resolution</u>. In the event that the Parties are unable to agree upon any disputes arising under this Agreement, including without limitation any claims of breach that may give rise to termination, the Parties' relationship managers agree to negotiate in good faith to resolve any such disputes. If such negotiations and meetings do not resolve the dispute within [\*\*] days after notice of the dispute, then a senior executive from each Party will meet face to face within [\*\*] days or as mutually agreed between them to attempt to resolve such dispute. If the dispute is not resolved to the satisfaction of these executives within [\*\*] days, then either Party may pursue all available legal remedies. Notwithstanding the foregoing, either Party may seek injunctive relief with respect to any disputed matter without following the dispute resolution procedure set forth above.
- c. Exhibits. The following Exhibits attached to this Agreement are deemed a part of this Agreement and incorporated by reference herein:

EXHIBIT A PRODUCT

EXHIBIT B INITIAL ORDERS

EXHIBIT C QUALITY AGREEMENT

EXHIBIT D MEMORANDUM OF INSURANCE

EXHIBIT E STATEMENTS OF WORK

EXHIBIT F LIST OF PATENTS

EXHIBIT G CONFIDENTIALITY AGREEMENT

EXHIBIT H PROCESS OVERVIEW

EXHIBIT I COMMERCIAL SUPPLY AGREEMENT TERMS

EXHIBIT J PRICING

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

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e. <u>Assignment</u>. Except as otherwise provided in this Section 16(e), neither this Agreement nor any part hereof may be assigned or transferred by either Party, whether by operation of law or otherwise, without the other Party's prior written consent. Either Party shall have the right to assign this Agreement, without the other Party's consent, in the event of a sale or transfer of the business as to which this Agreement relates, whether such sale or transfer occurs by merger, reorganization, asset and/or stock purchase, or by any other means, provided that the assignee

agrees in writing to assume all of the assignor's obligations under this Agreement. The assigning Party shall notify the non-assigning Party in writing as soon as possible of any sale or transfer of its business. Any assignment or purported assignment in violation hereof shall be void. This Agreement will be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

- f. Headings; Construction; Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Exhibit, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (i) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (ii) any reference to any law refers to such law as from time to time enacted, repealed or amended; (iii) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (iv) the words "include," "includes," "including," "exclude," "excludes," and "excluding," shall be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import; and (v) all references in this Agreement to "days" will, unless otherwise specified he
- g. <u>No Third Party Beneficiaries</u>. No provisions of this Agreement are intended to confer or give, or will be construed to confer or give, to any person or entity other than Agilent and Customer any rights, remedies or other benefits under or by reason of this Agreement.
- h. <u>Severability</u>. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid or unenforceable in any respect, such determination will not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct. To the extent that any such provision is found to be invalid, illegal or unenforceable, the Parties will negotiate in good faith to substitute for such provision, to the extent possible, a new provision that most nearly effects the Parties' original intent in entering into this Agreement or to provide an equitable adjustment in the event no such provision can be added. The other provisions of this Agreement will remain in full force and effect.
- i. <u>Hierarchy Of Documents</u>. Unless otherwise specifically agreed to by the Parties, in the event of any conflict between the terms of this Agreement and its Exhibits, and a Purchase Order, the order of precedence is as follows: (i) the terms of this Agreement; (ii) its Exhibits; and (iii) the terms of

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the accepted Purchase Order. The Parties acknowledge and agree that the pre-printed provisions on any Purchase Order will be deemed deleted and of no effect whatsoever.

- j. <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior communications, representations or agreements, whether oral or written. No modifications, amendments, or waiver of any term, condition or provision of this Agreement will be binding on either Party unless in writing and signed by an authorized representative of each Party.
- k. <u>Governing Law</u>. This Agreement is made under and will be construed in accordance with the laws of New York without giving effect to that jurisdiction's choice of law rules. The United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement or to transactions processed under this Agreement.
- l. <u>Counterparts</u>. This Agreement may be executed in counterparts each of which, when executed and delivered, shall be original, but all such counterparts shall constitute one and the same document. The Parties agree that signatures transmitted via portable document format (PDF) shall be deemed originals until originals replace such copies.

APPROVED AND AGREED TO:

AGILENT TECHNOLOGIES, INC.		OPHTHOTECH CORPORATION		
By:	/s/ Nelson Thune	Ву:	/s/ Bruce Peacock	
Typed Name:	Nelson Thune	Typed Name:	Bruce Peacock	
Title:	General Manager	Title:	Chief Financial and Business Officer	
Date:	02 May 2014	Date:	May 2, 2014	
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[\*\*].

#### **EXHIBIT B**

## **INITIAL ORDERS**

Agilent SOW/Document

Number	Date	Title
Q09-12-77	SEP 21, 2012	[**]
Q01-13-31	JAN 15, 2013	[**]
Q05-13-74C	JUL 18, 2013	[**]
Q08-13-110	SEP 20, 2013	[**]

# **OPHTHOTECH**

PO# Purchase order

PO Date: 12 Oct 2012 Phone: [\*\*] **Contact:** [\*\*]

001-0032.

To: Agilent Technologies, Inc. 5555 Airport Blvd, Suite #100 Boulder, CO 80301

Attn: [\*\*] Tel: [\*\*] Fax: [\*\*]

Invoice & Ship To:

[\*\*] Ophthotech Corp. 5 Vaughn Drive, Suite 106

Princeton, NJ, 08540 Tel: [\*\*] Fax: [\*\*]

Invoices submitted against this PO will be paid within [\*\*] days of receipt.

Further to Agilent Quote # Q09-12-77, please supply and deliver the goods or services below as described in the quote:

Item	Quantity		Description	Unit Price	To	otal Price
1	[**]	[**]		[**]		[**]
2	[**]	[**]		[**]		[**]
3	[**]	[**]		[**]		[**]
4						
9						
				Subtotal	\$	[**]
				Tax		
				Total	\$	[**]

- Please send two copies of your invoice. 1.
- 2. Enter this order in accordance with the prices, terms, delivery dates, and specifications listed above.
- 3. Please notify us immediately if you are unable to ship/deliver as specified.

Authorized Signature: 12 Oct 2012 /s/ Bruce Peacock Date

Bruce Peacock CBO Title:

This order is not valid unless it is signed. Please acknowledge receipt of this order.

# **OPHTHOTECH**

Name:

**Purchase order** PO# 001-0035 PO Date: 24Jan2013 Phone: [\*\*]

**Contact:** 

#### To:

Agilent Technologies, Inc. 5555 Airport Blvd, Suite #100 Boulder, CO 80301

Attn: [\*\*] Tel: [\*\*] **Invoice & Ship To:** 

[\*\*] Ophthotech Corp. 5 Vaughn Drive, Suite 106 Princeton, NJ, 08540

Tel: [\*\*] Fax: [\*\*]

Invoices submitted against this PO will be paid within [\*\*] days of receipt

Per Agilent Quote #: Q01-13-31 with the following exceptions

- Release and In-process Specifications to be finalized
- Any credit with regard to the expedite fee from Agilent Quote Q09-12-77 to be discussed

Item	Q	uantity		Description		Unit Price	Total Price
1		[**]	[**]			[**]	[**]
2							
3							
4							
5							
						Subtotal	\$ [**]
						Tax	
						Total	\$ [**]
1. 2. 3.		in accorda	nce with the prices	s, terms, delivery dates, and spe le to ship/deliver as specified.	cifications listed above.		
Authoriz	zed Signature:	/s/ Samii	r Patel		Date	24 Jan13	
Name:		Samir Pa	atel				
Title:		CEO					
This ord	er is not valid unl	ess it is sig	ned. Please acknov	wledge receipt of this order.			

### **EXHIBIT C**

### **QUALITY AGREEMENT**





### **Quality Agreement**

### Use as an exhibit to service and supply agreement

Customer: **Ophthotech Corporation** One Penn Plaza New York, NY 10119 Supplier: Agilent Technologies, Inc. 5555 Airport Boulevard Boulder, Colorado 80301 E10030 (PEGylated oligonucleotide) CSN API Product(s): Services: Laboratory Testing · Manufacturing Support and Finished API Release and Stability (CTX)  $\cdot$  Finished Drug Product Release and Stability Testing (CTL) Version: 00

### **Approvals:**

/s/ Nelson Thune
Agilent Technologies General Manager

11/4/13

Date

/s/ illegible	06 Nov 13
Agilent Manufacturing	Date
/s/ Celeste O'Connor	08 Nov 13
Agilent Technologies Quality Assurance	Date
/s/ Douglas Brooks	06-Nov-2013
Ophthotech Manufacturing	Date
/s/ Douglas Kollmorgen	05-Nov-2013
Ophthotech Quality Assurance	Date
Other	Date
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Ophthotech: QA-AGR-0001 V00 Agilent: QA-CON-0021	ENTIAL
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### Sections: (aligned to May 2013 FDA DRAFT Guidance)

- 1. Purpose and Scope
- Terms
  - 2.1. (3) Definitions
  - 2.2. (21) Audits and Inspections
  - 2.3. (2) Roles and Communications
  - 2.4. (19) Subcontracting
  - 2.5. (17) Complaints, returns and recalls
  - 2.6. (22) Quality Agreement Modifications
- 3. Quality Dispute Resolution
- 4. Responsibilities, including communication mechanisms and contacts
  - 4.1. (4) General Responsibilities
  - 4.2. Quality Unit Responsibilities
  - 4.3. Facilities and Equipment
    - 4.3.1. (12) Facility
  - 4.4. Materials Management
    - 4.4.1. (8) Raw Materials
    - 4.4.2. (18) Reprocessing and Reworking
  - 4.5. Product Specific Terms
    - 4.5.1. (10) Manufacturing
    - 4.5.2. (11) Qualification and Validation
  - 4.6. Laboratory Controls
    - 4.6.1. (15) Reference Standards
    - 4.6.2. (9) Specifications and Test Methods
    - 4.6.3. (14) Samples
    - 4.6.4. (16) Stability
    - 4.6.5. (13) Packaging, Labeling, Testing and Release of GMP API
  - 4.7. Documentation
    - 4.7.1. (7) Documentation
    - 4.7.2. (20) Regulatory Submission
- Change Control and Revisions
  - 5.1. (5) Change Management
  - 5.2. (6) Deviation Handling and OOS Investigation
- 6. (23) Attachments
  - 6.1. Contact Information

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### 1. Purpose and Scope

- 1.1. This Quality Agreement ("Agreement") for the clinical and commercial stage manufacturing of Active Pharmaceutical Ingredients (API), and testing of API and Drug Product under Good Manufacturing Practice (GMP) is being executed by and between:
  - · **Ophthotech Corporation** hereafter referred to as "Ophthotech".

- And, **Agilent Technologies, Inc**. hereafter referred to as "Agilent".
- 1.2. Agilent and Ophthotech are parties to Manufacturing and Supply Agreements as set forth in Attachment 2 (the "Supply Agreements"), pursuant to which Agilent is to supply Ophthotech API and perform certain Manufacturing and Laboratory Services with respect to API and Drug Product. This Agreement will become effective as of the date of the last signatory herein.
- 1.3. Agilent shall operate in accordance with GMP for manufacturing of GMP APIs and the performance of Manufacturing and Laboratory Services and such other applicable regulatory requirements as described in this Agreement and the applicable Supply Agreement. The purpose of this Agreement is to clearly define the roles and responsibilities of Agilent and Ophthotech with regard to quality and GMP compliance issues concerning the production of GMP API molecules and the performance of certain Manufacturing and Laboratory Services, including testing of API and Drug Product.
- 1.4. The scope of this Agreement includes GMP and quality compliance associated with the clinical and commercial stage manufacturing of GMP API molecules and the performance of certain Manufacturing and Laboratory Services, including testing of API and Drug Product.

#### 2. Terms

- **2.1. (3) Definitions** 
  - 2.1.1. **Analytical (Test) Methods** Methods used for analytical testing, including Standard Test Methods and Compendial Methods.
  - 2.1.2. **Active Pharmaceutical Ingredient (API),**—Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the Drug Product as defined in ICH Q 7. Such substances are intended to furnish pharmacological activity or other direct effect on the diagnosis, cure mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

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- 2.1.3. **Approval** The term "Approval" is defined as concurrence between Ophthotech and Agilent, as evidenced in writing and signed by both companies' Authorized Quality Representatives. In certain cases, Approvals may be obtained electronically or verbally, followed by a written confirmation.
- 2.1.4. **Authorized Quality Assurance Representative** An individual named within this Agreement with the authority to resolve any disputes or conflicts relating to this Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements.
- 2.1.5. **Batch** A specific quantity of material produced in a process or series of processes that is expected to be homogeneous, within specified limits, and that is produced by Agilent in the same cycle of manufacture as defined by the applicable batch record and which shall be packaged and released with a single release and lot number.
- 2.1.6. **Batch Packet** Relevant documentation to be transferred by Agilent to Ophthotech to support the release of a Batch. This packet includes, but is not limited to, copies of:
  - 2.1.6.1. Executed Batch Records
  - 2.1.6.2. all Deviations, including proposed CAPA's where appropriate, associated with the manufactured API
  - 2.1.6.3. OOS investigations associated with analysis of the API
  - 2.1.6.4. In-process results
  - 2.1.6.5. Certificate of Analysis (COA)
  - 2.1.6.6. Certificate of Compliance (COC)
  - 2.1.6.7. QA disposition
- 2.1.7. **Batch Production Record** An accurate reproduction of a Master Batch Record used as instruction for and documentation of production activities.
- 2.1.8. **CAPA-**Corrective action, preventative action.
- 2.1.9. **Certificate of Analysis (COA)** A document, signed by an authorized representative of Agilent, describing (i) the Specification; (ii) the testing methods applied to the API in order to verify compliance with the Specification, and (iii) the results thereof.
- 2.1.10. **Certificate of Compliance (COC)** A document, signed by an authorized quality assurance representative of Agilent, attesting that a particular Batch was manufactured in accordance with cGMP, and the Specification. The Certificate of Compliance may be included

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within the Certificate of Analysis, or separately, if required by Ophthotech.

2.1.11. **cGMP or GMP** — Current Good Manufacturing Practices pursuant to (i) the U.S. Federal Food, Drug, and Cosmetic Act as amended (21 USC 301 et seq.), (ii) relevant U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations (including but not limited to Parts 11, 210, 211, 600 and 610), (iii) Commission Directive 2003/94/EEC of 08 October 2003, (iv) the EC Guide to Good Manufacturing Practice for Medicinal Licensed Products, including respective guidance documents; (v) any

comparable laws, rules or regulations of other jurisdictions as mutually agreed to by Ophthotech and Agilent, as each may be amended from time to time; and (vi) the relevant current International Conference on Harmonization (ICH) guidance documents, including the ICH Guidance Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients and ICH Guidance Q11

- 2.1.12. Controlled Documents Paper or electronic documents that are part of the quality system and contain data/information required by cGMPs. These documents may also be referred to as GMP documents. Such documents must be initiated and revised through document control and/or change control procedures. Examples of controlled documents are: SOPs, analytical test methods, specifications, batch records, validation protocols, forms, etc.
- 2.1.13. **Critical Raw Material** A material (starting materials, reagents and solvents) whose intended use is in the production of intermediates or APIs and whose attributes must be controlled within predetermined criteria to ensure that the API meets its specification.
- 2.1.14. **Deviation** A departure from written standard where any of the following is true: requires investigation and root cause analysis, has the potential for product, process, or equipment impact, requires CAPA for prevention of future recurrence, requires a Change Control, or presents a potential non-conformance with a regulatory filing, specification, or validated parameter, or requires customer notification.
- 2.1.15. **Disposition** The action of assigning a status of release, quarantine, reject etc. to a material.
- 2.1.16. **Drug Product** The dosage form in the final immediate packaging intended for human clinical or commercial use.
- 2.1.17. **Executed Batch Record** A completed Batch Production Record.

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- 2.1.18. **Intermediate** A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated.
- 2.1.19. **Master Batch Record (MBR)** The document that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the manufacture and testing of the API.
- 2.1.20. **Out-of-Specification (OOS)** A result derived from testing that is valid but does not comply with the established specification. In this case, "result" is defined as the final reportable value as determined according to the test method. Such a reportable value may be comprised of multiple individual determinations (i.e., replicates) as per the test method. Only reportable values are compared to specifications; therefore only a reportable value may constitute an OOS.
- 2.1.21. **Product** Any a) API, or (b) Drug Product comprised of API, or (c) intermediate(s) of (a) or (b), in each case as specified in the applicable Scope.
- 2.1.22. **Qualified Supplier** A supplier who has met minimum approval standards and been qualified by Agilent, to provide required items or services that may impact API quality.
- 2.1.23. **Raw Material** A general term used to denote starting materials, reagents, and solvents intended for use in the production of intermediates or APIs.
- 2.1.24. **Regulatory Authority**-means any competent authority of the US, Europe, Japan, or other regulated region which regulates the manufacture of the API in accordance with ICH guidelines.
- 2.1.25. **Significant Change** Any change that: has the potential to (a) impact the quality, safety, identity, strength, efficacy, potency or purity of the API; (b) impact the regulatory commitments and/or reporting requirements of the API; (c) require re-qualification or re-validation of the process, methods, reference standards approved by Ophthotech; and/or (d) result in changing or modifying Ophthotech's approved Specifications, test methods or any document approved by Ophthotech.
- 2.1.26. **Significant Deviation** A deviation that has been shown to adversely impact final API, stability study, drug product or a critical raw material.
- 2.1.27. **Specification** The Specification for the Product as set forth in the Statement of Work, which Specification may be amended from time to time in accordance with this agreement.

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2.1.28. **Subcontractor** - Any manufacturer, packager, or other API support service provider who performs processing, packaging, or testing of an API or any intermediate step of manufacture, or other API support service on behalf of Agilent.

### 2.2. (21) Audit and Inspections

2.2.1. Agilent agrees to allow the FDA and any other Regulatory Authority to conduct any inspection related to the manufacture of the API which the FDA or such Regulatory Authority requires and Agilent agrees to reasonably cooperate with the FDA or such Regulatory Authority in connection with such inspection. Agilent agrees to promptly notify Ophthotech of any inspections or actions by a Regulatory Authority which could potentially impact the production or distribution of the GMP API; provided that

Agilent shall provide notice to Ophthotech of any such inspection or action that relates to the API or Product testing within [\*\*] hours. Ophthotech may be present during any regulatory inspections involving their Product. Agilent agrees to provide Ophthotech (i) copies of any report issued and notice of any regulatory actions resulting from such inspections within [\*\*] business days of any written action from such Regulatory Authority and (ii) within [\*\*] days after Agilent's receipt of such regulatory action, a plan to make corrective actions to remedy such regulatory action (which plan Agilent shall promptly implement and diligently pursue).

- 2.2.2. Ophthotech reserves the right to conduct compliance audits of Agilent's records and relevant areas of the Agilent facility that are involved in the production, testing, or storage of the API and Intermediates. Agilent requires a minimum of [\*\*] business day notice for compliance audits. During audits, Agilent shall provide Ophthotech with all relevant documentation for the sole purpose of assuring API quality and compliance with agreed-upon manufacturing procedures.
- 2.2.3. Ophthotech is entitled to one routine on-site GMP audit per [\*\*] period provided active manufacturing occurs during this period. A request for audit due to a specific issue ('for-cause' audit) may be conducted at any time with a minimum of a [\*\*] business day notice and must be focused only on the subject of the 'for-cause' audit.
- 2.2.4. During an audit by Ophthotech, any non-conformances will be noted and documented in a report issued by Ophthotech within ([\*\*] business days. Agilent will formally respond in writing within [\*\*] business days following receipt of the report [\*\*].
- 2.2.5. Ophthotech reserves the right, at Ophthotech's expense, to conduct PAI readiness and mock audit exercises at Agilent.

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#### 2.3. (2) Roles and Communication

- 2.3.1. Ophthotech and Agilent will each appoint a Primary Contact for communications between the two parties and who will jointly be responsible for the coordination and management of the project, including communication of quality and regulatory matters pursuant to this Agreement.
- 2.3.2. Both primary contacts will be included on all communications between Agilent and Ophthotech. For verbal communications regarding quality and regulatory matters, the initiating party will summarize the discussion in a written record, which will then be distributed by the respective primary contact.
- 2.3.3. Ophthotech and Agilent will each appoint an Authorized Quality Assurance (QA) Representative who will serve as the primary contact for quality related notifications between the two parties.
- 2.3.4. Responsible personnel are identified in Attachment 23.1. Either party may change its Project Manager or Authorized Quality Assurance Representative by providing the other party written notice and Attachment 23.1 shall be updated to reflect any such change(s).

### 2.4. (19) Subcontracting

- 2.4.1. Agilent shall use approved subcontractors according to internal procedures. Agilent will not subcontract any activities related to the GMP manufacturing or testing using non-approved subcontractors of API without prior approval of Ophthotech.
- 2.4.2. Agilent shall ensure that any quality impacting changes proposed at a subcontractor site utilized for Ophthotech testing are assessed and Ophthotech notified prior to the change being made.

### 2.5. (17) Complaints, Returns, and Recalls

- 2.5.1. Customer Complaints Agilent agrees to maintain appropriate systems for documenting and investigating any customer complaints associated with the GMP API. Agilent will assist Ophthotech with investigational work to resolve the complaint. Agilent will respond within one business day for any serious or patient safety related API complaints. In the case of an emergency Agilent will rely upon site procedures to respond.
- 2.5.2. GMP API Returns Agilent will maintain records for returned products including batch number, quantity and reason.
- 2.5.3. Recalls Ophthotech will be responsible for the recall of any marketed Drug Products. Agilent is responsible for notifying

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Ophthotech of any GMP API that is the subject of a recall. During a Product recall, withdrawal, or field correction, Agilent shall keep accurate drug accountability and distribution records, fully cooperate with Ophthotech in notifying customers, and conducting the necessary recall and investigational activities. Agilent shall provide assistance in the investigation reasonably required to determine the cause and extent of the problem necessitating the recall.

### 2.6. (22) Quality Agreement Revisions

2.6.1. Any revision to this Quality Agreement or any related attachments must be approved in advance by both parties. Revisions will be documented as written addendums that are attached to the original Quality Agreement. Each addendum will minimally be approved by the Primary Contact and the Quality Assurance representatives from both companies.

2.6.2. The Quality Agreement shall be updated and will minimally be approved by the Primary contact and the Quality Assurance representatives from both companies at the initiation of Ophthotech every [\*\*] years.

#### 3. Quality Dispute Resolution

- 3.1. In the event of a dispute as to whether (i) the Product has a Latent Defect or (ii) the Product was not in Good Condition at the time of delivery, the parties shall follow the dispute resolution procedure set forth the applicable Supply Agreement. In the unlikely event a dispute arises regarding any other issue affecting product quality that cannot be resolved, the parties agree to resolve the dispute in the following manner.
  - 3.1.1. The parties agree to establish the basis of the dispute in writing within [\*\*] days of the origin of the dispute.
  - 3.1.2. The parties agree to the description content and detail of the dispute by signing and dating the dispute description document.
  - 3.1.3. The document is escalated to the next higher comparable level in both organizations wherein parties from both companies are tasked with resolving the dispute as written.
  - 3.1.4. In the event the escalation does not resolve the dispute the parties agree to follow the dispute resolution procedure set forth for Escalated Dispute Resolution the applicable Supply Agreement.

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### 4. Responsibilities, including communication mechanisms and contacts

#### 4.1. (4) General Responsibilities

- 4.1.1. Agilent agrees to manufacture, test, and deliver the GMP API in accordance with cGMP and other applicable compliance standards.
- 4.1.2. Agilent agrees to test and perform stability studies on either API or Drug Product as denoted in applicable Statements of Work.
- 4.1.3. Agilent agrees to maintain and operate under a quality system consistent with US and EU cGMP, including maintaining standard operating procedures ("SOPs"), training and root cause analysis and corrective & preventive actions.
- 4.1.4. Agilent agrees to ensure that personnel involved in the manufacture, testing and disposition of the GMP API have the education, training and experience, or any combination thereof, to enable those persons to perform their assigned responsibilities. Training extends to the particular operations that the employee performs and to the applicable GMP's as they relate to API and Drug Product and the employee's functions. Training records shall be maintained by Agilent as required by GMP and made readily available for the personnel working on API and Drug Product. All training relative to a specific task will be completed prior to the initiation of the task. Training will be conducted with sufficient frequency to assure familiarity with requirements applicable to the position and function. Agilent will ensure that any necessary GMP or technical training has been performed and is documented.

### 4.2. Quality Unit Responsibilities

- 4.2.1. The quality unit shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The responsibilities and procedures applicable to the quality unit shall be in writing; and the written procedures shall be followed.
- 4.2.2. The quality unit shall be responsible to assure adequate testing facilities are available and utilized for the testing of raw materials, components, API containers, closures, packaging materials, in-process materials, and drug products.
- 4.2.3. The quality unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

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### 4.3. (12) Facilities and Equipment

- 4.3.1. Agilent will manufacture the Ophthotech API only at the Agilent facility located at 5555 Airport Blvd. Boulder, CO 80301. ("Facility")
- 4.3.2. All critical measuring and monitoring devices used in processing equipment will be calibrated according to a pre-determined documented schedule. As appropriate, calibrations will be conducted using standards that are traceable to NIST or an appropriate, traceable standard.
- 4.3.3. All GMP manufacturing operations will occur in equipment and facilities that are fully qualified per the Agilent Validation Master Plan and are subject to formal maintenance, calibration, and cleaning procedures.
- 4.3.4. The facility will be maintained according to procedure to ensure a state of compliance and maintain a validated state relative to the manufacturing of GMP APIs and in the performance of Manufacturing and Laboratory Services.

4.3.5. Any proposed change in the facility that has the potential to impact the quality of the Ophthotech API will be communicated to Ophthotech prior to the change being made.

#### 4.4. Materials Management

#### 4.4.1. (8) Raw Materials

- 4.4.1.1. It is the responsibility of Agilent to handle procurement, delivery, inspection, testing and storage of raw materials (including components) that are used to produce the GMP API except as specified in 4.4.1.6. Materials will be tested and/ or examined against approved specifications.
- 4.4.1.2. Materials of animal origin will be certified BSE/TSE free as per Agilent internal procedures.
- 4.4.1.3. All Critical Raw Material suppliers will be qualified as appropriate to the stage of development and the regulatory status of the GMP API as per Agilent internal procedures. Agilent will select suppliers for non-critical raw materials and components in accordance with the use and after assessment by Agilent Quality.
- 4.4.1.4. The testing procedures for the Critical Raw Materials will be performed per compendial methods or other test methods developed by Agilent if a compendial testing is not available or applicable.

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- 4.4.1.5. Agilent shall use only those suppliers of Critical Raw Materials that have been approved by Agilent. If Ophthotech requests a specific supplier that is not a current Agilent qualified supplier, Agilent and Ophthotech will work together to qualify that supplier.
- 4.4.1.6. Except as otherwise agreed to by the Parties in writing, if Ophthotech supplies material to Agilent for API manufacture, it is Ophthotech's responsibility to qualify that supplier and provide qualification documentation to Agilent, including BSE/TSE certification and such qualification and audit records as agreed to by the Parties.
- 4.4.1.7. Agilent will maintain a Supplier Qualification program that may be assessed by Ophthotech during a quality audit.
- 4.4.1.8. Agilent will maintain samples of Critical Raw Materials, API and finished Drug Product in accordance with ICHQ7. All materials shall be handled and stored in accordance with the approved specifications.
- 4.4.1.9. Under no circumstances shall any materials which may present a potential hazard to the raw materials utilized in API be stored in the Facility, or in proximity to the area where raw materials utilized in API are maintained. If such materials are stored in the Facility, the Parties must agree to their separation and segregation.

### 4.4.2. (18) Reprocessing and Reworking

4.4.2.1. If either Ophthotech or Agilent determines that reprocessing or reworking of the GMP API is necessary due to OOS, manufacturing deviation, unmet Specifications, or otherwise, the procedure will be documented and approved by Agilent Chemical Development, Agilent Manufacturing, Agilent QA and Ophthotech QA, provided that Agilent shall not reprocess or rework the GMP API without the prior written consent of Ophthotech.

### 4.5. Product Specific Terms

#### 4.5.1. (10) Manufacturing

4.5.1.1. Master Batch Record (MBR) - GMP APIs will be manufactured in accordance with written MBRs that have been drafted by Agilent and approved by Ophthotech. MBRs will be reviewed and approved by the Agilent QA

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- department prior to use. Executed Batch Records will be reviewed and approved by the Agilent QA department prior to disposition to Ophthotech.
- 4.5.1.2. Waste Handling Any waste generated by the process will be disposed of according to Agilent procedures and in a secure and legal manner which prevents unauthorized use and/or environmental compliance problems.

### 4.5.2. (11) Qualification and Validation

- 4.5.2.1. Agilent will be responsible for the qualification and validation of manufacturing and testing equipment and processes, as mutually defined by Agilent and Ophthotech.
- 4.5.2.2. Agilent will perform qualification and/or validation, when applicable, of any analytical test methods as required by Ophthotech. Agilent will be responsible for generating protocols to qualify/validate the test methods which will be reviewed and approved by both Agilent and Ophthotech, if required. Agilent will provide a final report to Ophthotech for method transfer, qualification, and/or validation.

- 4.5.2.3. Agilent will not make a Significant Change to any Ophthotech specific test method without prior approval from Ophthotech. Compendial updates to methods are acceptable and will not require Ophthotech pre-approval. Ophthotech will be notified of changes to generic methods (other than compendial methods) used for the Ophthotech process and copies provided on request.
- 4.5.2.4. Ophthotech is responsible for providing Agilent with sufficient quantities of an appropriately qualified API reference standard along with a reference standard qualification certificate or appropriately tested reference material. Agilent can also be requested to prepare an API reference standard as described in section 4.6.1.2

#### 4.6. Laboratory Controls

#### 4.6.1. (15) Reference Standards/ Materials

4.6.1.1. Any reference standards / materials that are supplied by Ophthotech or obtained from an official source will be stored and used in accordance with established Agilent procedures and any written instructions provided by Ophthotech.

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- 4.6.1.2. Any reference standards/ materials produced in-house at Agilent for Ophthotech will be appropriately documented and tested to ensure appropriate characterization of the material.
- 4.6.1.3. (Copy of foregoing section) Ophthotech is responsible for providing Agilent with sufficient quantities of an appropriately qualified API reference standard along with a reference standard qualification certificate or appropriately tested reference material. Agilent can also be requested to prepare an API reference standard as described in section 4.6.1.2

### 4.6.2. (9) Specifications and Test Methods

- 4.6.2.1. Agilent will follow written quality system procedures for the identification, quarantine, handling, sampling, testing and approval or rejection of materials. Agilent will perform testing per established methods/procedures and review results against the Specifications. Changes to these methods and procedures will be consistent with the Change Management section of this Agreement. Deviations to the test methods and procedures and OOS results will be handled in a manner consistent with the Deviation and OOS sections of this agreement.
- 4.6.2.2. Critical Raw Materials Agilent will make recommendations for any change in Critical Raw Material Specifications and test methods as necessary to assure quality and compliance. The establishment of formal Critical Raw Material Specifications and test methods will occur per Agilent's internal procedures.
- 4.6.2.3. In-Process Ophthotech and Agilent will agree on in-process Specifications and test methods used during development. The establishment of in-process Specifications and test methods for validation and commercial manufacturing will occur per Agilent's internal procedures and shall be subject to approval by Ophthotech.
- 4.6.2.4. Analytical Data Reporting Requirements Copies of all analytical QC raw data (including chromatograms) and reports generated by Agilent will be provided to Ophthotech with the Batch Packet for in-process and final API analysis following manufacture. Copies of data related to method transfer or validation will be available

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for on-site review by Ophthotech and provided to Ophthotech as required.

### 4.6.3. (14) Samples / Reserve

- 4.6.3.1. Raw Materials Agilent agrees to sample and retain sufficient amounts and stored under controlled conditions, of all materials used in processing and testing, except water, compressed gasses and any highly volatile compounds and compounds that are not stable. In addition to the above, it is the responsibility of Agilent to retain Critical Raw Material samples with appropriate labeling, storage and duration according to Agilent procedures.
- 4.6.3.2. In-Process Agilent will retain in-process samples until the Batch has been approved for release or as requested by Ophthotech in writing.
- 4.6.3.3. Final GMP API Agilent will obtain retain samples of the final GMP API in accordance as requested by Opthotech in writing, but at a minimum, in sufficient amount to comply with ICH Q7 guidance for API sample retains. These retention samples will be packaged and stored in accordance with ICH Q7 and the Agilent specification. Agilent will notify Ophthotech prior to disposing of retain samples as per Agilent internal procedures.

### 4.6.4. (16) Stability

- 4.6.4.1. Stability testing, both accelerated and long-term, will be conducted as contracted by Ophthotech. Ophthotech will be responsible for determining appropriate retest/expiry dates, storage conditions, and packaging materials.
- 4.6.4.2. Stability testing will be conducted under protocols written by Agilent and approved by Ophthotech and Agilent QA prior to commencement of the stability study.

#### 4.6.5. (13) Packaging, Labeling, Testing and Release of GMP API

- 4.6.5.1. The final packaging, labeling, and testing of each GMP API Batch will be conducted in accordance with written procedures, and with packaging and labeling requirements and test specifications provided by Ophthotech.
- 4.6.5.2. Each batch will be internally released by the Agilent QA department as per established internal procedures which will include a review of associated batch records and analytical data.
- 4.6.5.3. A Certificate of Analysis (COA) will be issued by Agilent for each Batch of API confirming that the API has been tested in accordance with the Specification using approved methods. The COA will contain results for all API analyses that have a Specification. Agilent will provide an Analytical Data Report Form for any additional analyses not listed on the Specification.
- 4.6.5.4. A Certificate of Compliance (COC) will be issued by Agilent for each Batch of API confirming that the API has been manufactured, packaged and tested in full compliance with GMP, ICH Q7 and local Regulatory requirements. The COC will attest to the accuracy of the manufacturing records and provide limited detail on the occurrence and resolution of deviations that may have occurred during Batch processing and testing. BSE/TSE certification for any animal derived raw materials, packaging components and processing aids is also provided.
- 4.6.5.5. Final release authority for shipment of each Batch of GMP API to Ophthotech will reside with Agilent's QA department.

#### 4.7. Documentation

- 4.7.1. (7) Documentation
- 4.7.2. The Agilent Primary Contact will provide and receive all controlled documents to and from the Ophthotech Primary Contact.
- 4.7.3. Agilent will generate any internal Controlled Documents necessary to support GMP API production and will be responsible for the retention and storage of all Batch Packet documentation in a secure QA archive according to Agilent's record retention policy.

  Ophthotech shall be notified prior to destruction of any Controlled Documents supporting a batch production record and have the option of making

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- arrangements for continued retention or the return of such documents to Ophthotech.
- 4.7.4. A Certificate of Analysis (COA), Certificate of Compliance (COC), BSE/TSE Certification, and Material Safety Data Sheet or Safety Data Sheet (MSDS/SDS) will be provided by Agilent with every GMP API shipment. Copies of completed Batch Packets documents will be provided to Ophthotech as defined in Section (2).
- 4.7.5. Controlled Documents specific to the manufacture of E10030 will be reviewed and approved by Ophthotech prior to Agilent making the documents effective.
- 4.8. (20) Regulatory Interactions and Submissions
  - 4.8.1. Regulatory Contacts. Unless otherwise required by applicable law, Ophthotech will be solely responsible for all contacts and communications with any regulatory authorities with respect to matters relating to the API or any of the Manufacturing and Laboratory Services under a Statement of Work. Agilent will notify Ophthotech immediately, and in no event later than [\*\*] days, after Agilent receives any contact or communication from any regulatory authority relating in any way to the API or Product testing or the Manufacturing and Laboratory Services under a Statement of Work and will provide Ophthotech with copies of any such communication within [\*\*] of receipt of such communication by Agilent. Agilent will consult with Ophthotech regarding the response to any inquiry or observation from any regulatory authority relating in any way to the API or Product testing or the Manufacturing and Laboratory Services under a Statement of Work and will allow Ophthotech at Opthotech's discretion to participate in any further contacts or communications relating to such Services. Agilent will comply with all reasonable requests and take into consideration all comments by Ophthotech with respect to all contacts and communications with any regulatory authority relating in any way to the API the Manufacturing and Laboratory Services under a Statement of Work.
  - 4.8.2. Submissions. Agilent will provide to Ophthotech at Ophthotech's expense, input, data and written content regarding the manufacturing and controls for the API as may be required for regulatory submissions. As the drug sponsor, it is the responsibility of Ophthotech to provide an appropriate template and specific content requests to Agilent.

#### 5. Change Control and Revisions

- 5.1. (5) Change Management
  - 5.1.1. Agilent will utilize a documented change control system as defined by internal procedures to control changes to raw materials, packaging materials, suppliers, equipment, manufacturing procedures, material specifications, facilities, sampling procedures, analytical methods, a process or method validated state or standard operating procedures.
  - 5.1.2. Any Significant Change or other change proposed by Agilent to the MBR, Facility, Utilities, Equipment, Specifications and/or SOPs, including but not limited to the manufacturing process, materials and/or analytical methods which may affect the quality or performance of the API over its shelf-life, acceptance criteria not met for post-validation batches or affect commitments made in regulatory filings (a) shall be made only as permissible under the applicable Supply Agreement and this Quality Agreement; and (b) must be approved by Ophthotech, in writing, prior to implementation for routine production or release of any affected batch.
  - 5.1.3. Ophthotech will use reasonable efforts to respond to any written request for change from Agilent within [\*\*] business days. If the change request is part of an initiated manufacturing campaign, Ophthotech will use reasonable efforts to respond within [\*\*]. No Significant Change shall be implemented by Agilent without the prior written approval of Ophthotech.
  - 5.1.4. Ophthotech initiated requests for changes shall be communicated to Agilent's Quality management in writing using Ophthotech's change control documentation. Agilent will use reasonable efforts to respond to any written request for change from Ophthotech within [\*\*] business days. Such Ophthotech requested changes shall, upon mutual agreement of the Parties, be implemented by Agilent using Agilent's current approved change management procedures. Agilent shall not unreasonably withhold, condition or delay its approval of any such change and any such changes required in order to comply with applicable laws, rules or regulations shall not require such approval, without reasonable justification.
- 5.2. (6) Deviation Handling and OOS Investigations
  - 5.2.1. Any deviations from approved manufacturing, testing, or storage procedures that occur in the course of batch production will be managed according to Agilent's internal procedures for deviation handling, and the extent of investigation will be determined by Agilent and shall be commensurate with the severity of the deviation and the potential API quality impact. Agilent must notify Ophthotech within [\*\*] business days from the observation of Deviations ([\*\*] with respect to Significant Deviations). All deviations will be investigated and fully documented by Agilent. This documentation will be retained

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- as part of the batch documentation for the batch affected. When deemed necessary, Ophthotech reserves the right to request additional or more in-depth investigation of the Deviation by Agilent. Ophthotech prior approval shall be obtained in writing for any planned Significant Deviation. Agilent shall not release any Batch which includes a Deviation.
- 5.2.2. All deviations will be assessed for potential API quality impact according to Agilent internal procedures and will be fully documented by Agilent. Investigations will include appropriate justification, scientific rationale and supporting data.
- 5.2.3. Agilent will notify Ophthotech of confirmed OOS results within [\*\*] business day of notification to Agilent QA that the OOS has occurred. Agilent will perform the OOS investigation as per Agilent internal procedures. Agilent shall provide Ophthotech written notice of any changes to its SOPs or other internal procedures relating to OOS investigations and shall, upon Ophthotech's request, make such changed procedures available for Ophthotech review

### 6. (23) Attachments

6.1. Contact Information

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#### 6.1.1 ATTACHMENT 1 — CONTACT INFORMATION

### **Ophthotech Mailing Address:**

Ophthotech Corporation One Penn Plaza, 35<sup>th</sup> Floor New York, New York 10119

### **Ophthotech Contact Information**

Name	Title	Phone	E-Mail
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

### **Agilent Technologies Contact Information**

Name	Title	Phone	E-Mail
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

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6.2. Attachment 2

6.2.1. Manufacturing and Supply Agreements to be added as they are agreed

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### EXHIBIT D

### **MEMORANDUM OF INSURANCE**

#### MEMORANDUM OF INSURANCE

### MEMORANDUM OF INSURANCE

**DATE** 10-Apr-2014

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of [\*\*] is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via [\*\*]. The information contained herein is as of the date referred to above. [\*\*] shall be under no obligation to update such information.

PRODUCER [**]	COMPANIES AFFORDING COVERAGE Co A [**]
INSURED	Со В
Agilent Technologies, Inc. 5301 Stevens Creek Blvd.	Co C
M/S 1B-08, Santa Clara	Co D
California 95051	
United States	

### **COVERAGES**

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE	POLICY EXPIRATION DATE	LIMITS LIMITS IN USD UNLESS OTHERWISE INDICA	ATED
A	GENERAL LIABILITY Commercial General Liability Occurrence	[**]	[**]	[**]	GENERAL AGGREGATE PRODUCTS - COMP/OP AGG PERSONAL AND ADV INJURY EACH OCCURRENCE FIRE DAMAGE (ANY ONE FIRE) MED EXP (ANY ONE PERSON)	[**] [**] [**] [**]

A	AUTOMOBILE LIABILITY Any Auto	[**]	[**]	[**]	COMBINED SINGLE LIMIT BODILY INJURY (PER PERSON) BODILY INJURY (PER ACCIDENT) PROPERTY DAMAGE	[**]
	EXCESS LIABILITY				EACH OCCURRENCE AGGREGATE	
	GARAGE LIABILITY				AUTO ONLY (PER ACCIDENT) OTHER THAN AUTO ONLY: EACH ACCIDENT AGGREGATE	
A	WORKERS	[**]	[**]	[**]		

COMPENSATIONWORKERS COMP LIMITSStatutory/ EMPLOYERSEL EACH ACCIDENT[\*\*]LIABILITYEL DISEASE - POLICY LIMIT[\*\*]THE PROPRIETOR /<br/>PARTNERS /<br/>EXECUTIVE OFFICERSEL DISEASE - EACH EMPLOYEE[\*\*]

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

#### MEMORANDUM OF INSURANCE

ARE Included

**DATE** 10-Apr-2014

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of [\*\*] is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via [\*\*] The information contained herein is as of the date referred to above. [\*\*] shall be under no obligation to update such information.

PRODUCER INSURED

[\*\*]

Agilent Technologies, Inc. 5301 Stevens Creek Blvd. M/S 1B-08, Santa Clara California 95051 United States

### ADDITIONAL INFORMATION

Work Comp/Employers Liability

<br /> All states coverage except [\*\*]

<br /> Work Comp excludes: [\*\*]

The Memorandum of Insurance Serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

### EXHIBIT E

## STATEMENTS OF WORK

Agilent SOW/Document Number	Date	Title
Q07-08-56	JUL 9, 2008	[**]
Q01-10-19B	JAN 22, 2010	[**]
Q02-10-23B	MAR 1, 2010	[**]
Q03-10-37	APR 7, 2010	[**]
Q04-11-58B	JUN 24, 2011	[**]
Q07-11-82	JUL 29, 2011	[**]
Q09-11-106	OCT 6, 2011	[**]
Q04-12-30	APR 19, 2012	[**]
Q07-12-49	JUN 24, 2012	[**]
Q08-11-92C	SEP 18, 2012	[**]
Q03-13-52B	MAY 17, 2013	[**]

Q03-13-55	MAR 21, 2013	[**]
Q12-12-24C	MAR 21, 2013	[**]
Q02-13-39	APR 2, 2013	[**]
Q11-12-12D	APR 29, 2013	[**]
Q08-13-99	AUG 13, 2013	[**]
Q08-13-109	AUG 23, 2013	[**]
Q08-13-101	SEP 11, 2013	[**]
Q08-13-116	SEP 30, 2013	[**]
Q12-13-15B	Jan 14, 2014	[**]
Q11-13-05B	Jan 27, 2014	[**]
Q01-14-26	Feb 11, 2014	[**]
Q02-14-34	Feb 12, 2014	[**]
Q01-14-23D	Feb 18, 2014	[**]

#### **EXHIBIT F**

#### **LIST OF PATENTS**

Title

**Filing Date** 

Pursuant to Section 9.6.1 of the Agreement, the following Patents that cover the Process are [\*\*]

[\*\*]

Patent/Application #

[\*\*]

Country/Treaty

[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]			
Country/Treaty	Patent/Application #	Title	Filing Date
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

[\*\*]

#### **EXHIBIT G**

### **CONFIDENTIALITY AGREEMENT**



### CONFIDENTIALITY AGREEMENT

This Agreement dated 22 March, 2011 (the "Effective Date"), between Ophthotech Corporation, a Delaware corporation ("Ophthotech") with offices at 5 Vaughn Drive, Suite 106, Princeton, New Jersey, 08540, and Agilent Technologies, a Delaware corporation ("Agilent") with office at 5555 Airport Blvd # 100, Boulder, CO 80301-2648

- 1. <u>Background</u>. Ophthotech and Agilent (hereinafter collectively referred to as the "Parties", respectively as the "Party") intend to engage in discussions relating to the development, manufacture, and testing of Ophthotech Drug Substance and Drug Products including E10030 and ARC1905 and other, as mutually agreed to between the Parties (the "Purposes"). In the course of these discussions it is anticipated that each Party will disclose or deliver to the other Party and to the other Party's contractors and designees,(collectively, the "Representatives") certain of its trade secrets or confidential or proprietary information for the purposes of enabling the other Party to perform its obligations under the Purposes. The Parties have entered into this Agreement in order to assure the confidentiality of such trade secrets and confidential or proprietary information in accordance with the terms of this Agreement. As used in this Agreement, the Party disclosing Proprietary Information (as defined below) is referred to as the "Disclosing Party"; the Party receiving such Proprietary Information is referred to as the "Recipient".
- 2. <u>Proprietary Information</u>. As used in this Agreement, the term "Proprietary Information" shall mean all trade secrets or confidential or proprietary information designated as such in writing by the Disclosing Party, whether by letter or by the use of an appropriate proprietary stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed by the Disclosing Party or the Disclosing Party's Representatives to the Recipient or the Recipient's Representatives. Notwithstanding the foregoing, information which is orally or visually disclosed to the Recipient by the Disclosing Party, or is disclosed in writing without an appropriate letter, proprietary stamp or legend, shall constitute Proprietary Information if (i) it would be apparent to a reasonable person, familiar with the Disclosing Party's business and the industry in which it operates, that such information is of a confidential or proprietary nature the maintenance of which is important to the Disclosing Party or if (ii) the Disclosing Party, within [\*\*] days after such disclosure, delivers to the Recipient a written document or documents describing such Proprietary Information and referencing the place and date of such oral,

visual or written disclosure and the names of the Representatives of the Recipient to whom such disclosure was made. In addition, the term "Proprietary Information" shall be deemed to include: (a) any notes, analyses, compilations, studies, interpretations, memoranda or other documents prepared by the Recipient or its Representatives which contain, reflect or are based upon, in whole or in part, any Proprietary Information furnished to the Recipient or its Representatives pursuant hereto; and (b) the existence or status of, and any information concerning, the discussions between the Parties concerning the possible establishment of a business relationship.

- 3. <u>Scope of Agreement</u>. This Agreement shall apply to all Proprietary Information disclosed between the Parties hereto from the Effective Date until third anniversary of the Effective Date.
- 4. <u>Use and Disclosure of Proprietary Information</u>. The Recipient and its Representatives shall use Proprietary Information only for the Purposes and such Proprietary Information shall not be used for any other purpose without the prior written consent of the Disclosing Party. The Recipient and its Representatives shall hold in confidence, and shall not disclose Proprietary Information; provided, however, that (i) the Recipient may make any disclosure of such information to which the Disclosing Party gives its prior written consent; and (ii) any of the Proprietary Information may be disclosed by the Recipient to its Representatives who need to know such information with the Purposes and who are informed of the confidential nature of such information and of the terms of this Agreement. In any event, the Recipient shall be responsible for any breach of this Agreement by any of its Representatives, and agrees, at its sole expense, to take reasonable measures to restrain its Representatives from prohibited or unauthorized disclosure or use of the Proprietary Information. Notwithstanding anything contained in this Agreement to the contrary, this Agreement shall not prohibit the Recipient from disclosing Proprietary Information of the Disclosing Party to the extent required in order for the Recipient to comply with applicable laws and regulations, provided that the Recipient provides prior written notice of such required disclosure to the Disclosing Party.
- 5. <u>Limitation on Obligations</u>. The obligations of the Recipient specified in Section 4 and 7 shall not apply, and the Recipient shall have no further obligations, with respect to any Proprietary Information to the extent that such Proprietary Information:
- (a) is generally known to the public at the time of disclosure or becomes generally known without the Recipient or its Representatives violating this Agreement;
  - (b) is in the Recipient's possession at the time of disclosure;

becomes known to the Recipient through disclosure by sources other than the Disclosing Party without such sources violating any confidentiality obligations to the Disclosing Party; or

- (c) is independently developed by the Recipient without reference to or reliance upon Proprietary Information.
- 6. <u>Ownership of Proprietary Information</u>. The Recipient agrees that it shall not receive any right, title or interest in, or any license or right to use, Proprietary Information or any Disclosing Party's patent, copyright, trade secret, trademark or other intellectual property rights therein, by implication or otherwise. Each of the Parties hereto represents, warrants and covenants that the trade secrets herein which it discloses to the other Party pursuant to this Agreement have not been stolen, appropriated, obtained or converted without authorization.
- 7. <u>Return of Proprietary Information</u>. The Recipient shall, upon the written request of the Disclosing Party, return to the Disclosing Party all Proprietary Information (and all copies and reproductions thereof). In addition, the Recipient shall destroy: (i) the part of any notes,

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reports or other documents prepared by the Recipient which contain Proprietary Information; and (ii) any Proprietary Information (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party. Alternatively, upon written request of the Disclosing Party, the Recipient shall destroy all Proprietary Information from the Disclosing Party (and all copies and reproduction thereof) and the part of any notes, reports or other documents prepared by the Recipient which contain Proprietary Information. Notwithstanding the return or destruction of the Proprietary Information, the Recipient and its Representatives will continue to be bound by their obligations specified in Section 4, 5 and 7.

#### 8. <u>Miscellaneous</u>.

- (a) This Agreement supersedes all prior agreements, written or oral, between the Patties relating to the subject matter of this Agreement. This Agreement may not be assigned modified, changed or discharged, in whole or in part, except by an agreement in writing signed by the Parties.
- (b) This Agreement will be binding upon and inure to the benefit of the Parties and their respective heirs, successors and assigns. Notwithstanding the forgoing, such heirs, successors and assignments shall not release such assigning Party from any of its obligations under this Agreement.
- (c) This Agreement shall be construed and interpreted in accordance with the internal laws of the State of New Jersey, without giving effect to the principles of conflicts of law thereof.
- (d) The provisions of this Agreement are necessary for the protection of the business and goodwill of the Patties and are considered by the Parties to be reasonable for such purpose. The Recipient agrees that any breach of this Agreement will cause the Disclosing Party substantial and irreparable injury and, therefore, in the event of any such breach, in addition to other remedies which may be available, the Disclosing Party shall have the right to specific performance and other injunctive and equitable relief.
- (e) The obligations of the Recipient specified in Section 4, 5 and 7 imposed by this Agreement shall continue until the [\*\*] anniversary of the Effective Date.
- (f) For the convenience of the Parties, this Agreement may be executed by facsimile and in counterparts, each of which shall be deemed to be an original, and both of which taken together, shall constitute one agreement binding on both Parties.

EXECUTED as of the day and year first set forth above.		
AGILENT TECHNOLOGIES		OPHTHOTECH CORPORATION
By: /s/ James Powell		By: /s/ Richard Everett
Name: James Powell		Name: Richard Everett
Title: General Manager NASD		Title: VP, CMC Operations
	4	

AMENDMENT #1
TO
CONFIDENTIALITY AGREEMENT
BY AND BETWEEN
AGILENT TECHNOLOGIES, INC.
AND
OPHTHOTECH CORPORATION

This Amendment # 1 ("Amendment") amends the Confidentiality Agreement by and between Agilent Technologies, Inc. ("Agilent") and Ophthotech Corporation ("Ophthotech") dated as of 22 March 2011 (the "Agreement").

Agilent and Ophthotech hereby agree to amend the Agreement as follows:

- 1. Section 3, Scope of Agreement, is hereby deleted in its entirety and replaced with the following:
  - "This Agreement shall apply to all Proprietary Information disclosed between the Parties hereto from the Effective Date until the tenth anniversary of the Effective Date."
- 2. Section 8(e) is hereby deleted in its entirety and replaced with the following:
  - "The obligations of the Recipient specified in Section 4, 5 and 7 imposed by this Agreement shall continue until the [\*\*] anniversary of the expiration or termination of this Agreement."
- 3. This Amendment shall take effect as of 22 March 2014.
- 4. This Amendment constitutes the entire agreement between the parties and incorporates all prior agreements and amendments by reference. Except as; expressly amended by this Amendment, all other terms and conditions of the Agreement shall remain in full force and effect. All capitalized terms used in this Amendment but not otherwise defined herein, shall have the meaning assigned to them in the Agreement.

### AGREED:

AGILEN	NT TECHNOLOGIES, INC.	OPHTHOTECH CORPORATION		
By:	/s/ Nelson Thune	By:	/s/ Barbara A. Wood	
Name:	Nelson Thune	Name:	Barbara A. Wood	
Title:	General Manager	Title:	SVP, General Counsel and Corporate Secretary	
Date:	<u>02 May 2014</u>	Date:	14 April 2014	

EXHIBIT H

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# [\*\*] PROCESS FLOW

Confidential Materials omitted and filed separately with the Securities and Exchange Commission.

A total of two pages were omitted. [\*\*].

### EXHIBIT I

#### **COMMERCIAL SUPPLY AGREEMENT TERMS**

Terms used but not defined below shall have the meaning set forth in the Agreement.

<u>Exclusivity</u>. During the term of the Commercial Supply Agreement and for a period of five (5) years thereafter (subject to the termination provisions as mutually agreed to by the Parties), Agilent will only supply Anti-PDGF Aptamer APIs to Customer and any Affiliate of Customer or Third Party designated by Customer.

<u>Primary Supplier</u>. During the term of the Commercial Supply Agreement, Customer will purchase from Agilent at least [\*\*] percent ([\*\*]%) of its requirements of Product for use in the United States, European Union, and any additional future jurisdictions as mutually agreed to by the Parties in writing ("Territory").

<u>Capacity</u>. In the event that the Product gains regulatory approval, Agilent will provide capacity to manufacture accepted purchase orders for up to [\*\*] Kilos of Product per calendar year for Ophthotech's needs. Should [\*\*] Kilos of Product no longer be sufficient, the Parties will negotiate in good faith increased capacity to be dedicated to Ophthotech.

<u>Pricing</u>. Pricing for the Product will be negotiated in good faith by the Parties. Pricing for the Product shall be structured on a tiered basis with the price reduced as the volume ordered increases and the process is scaled up to produce larger volumes per batch. Pricing for the Product shall not exceed the pricing for Product as set forth in Exhibit J except to the extent that the Manufacturing Standards as of the Effective Date are materially modified pursuant to the Change Management provisions set forth in the Quality Agreement. In the event of any such change in the Manufacturing Standards, any increase in pricing shall be proportionate to the increase in Agilent's costs to manufacture Product based on such modified Manufacturing Standards.

<u>Supply Failures</u>. The Commercial Supply Agreement will include provisions detailing the rights and obligations in the event that Agilent fails to supply specified percentages of Product ordered by Customer under the Commercial Supply Agreement during a defined period of time, which rights will include a release from Customer's obligation to purchase [\*\*]% of its requirements of Product for use in the Territory.

<u>Term.</u> The Commercial Supply Agreement will have an initial term that ends five (5) years from the date of Customer's first commercial sale of the approved Finished Product. After the initial term, the Commercial Supply Agreement will renew for an indefinite period. Either Party may terminate the Commercial Supply Agreement at the end of the initial term or during the renewal term provided, however, that it has given the other Party at least eighteen (18) months prior written notice of termination.

#### **EXHIBIT J**

### PRODUCT PRICING

Pursuant to Section 6.1 of the Agreement, the following table provides not to exceed Product pricing based on quantities ordered via a single Purchase Order.

[**] [**] [**] [**] [**]	Quantity Ordered	Not to Exceed Price
[**]	[**]	[**]
l J	[**]	[**]
[**]	[**]	[**]
	[**]	[**]
[**]	[**]	[**]

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### **Execution Copy**

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

### LICENSING AND COMMERCIALIZATION AGREEMENT

### BY AND BETWEEN

### OPHTHOTECH CORPORATION

### AND

### **NOVARTIS PHARMA AG**

### MAY 19, 2014

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#### LICENSING AND COMMERCIALIZATION AGREEMENT

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This Licensing and Commercialization Agreement ("Agreement") is made and effective as of the 19th day of May, 2014 (the "Effective Date") by and between Ophthotech Corporation, a Delaware corporation, with offices at One Penn Plaza, 19<sup>th</sup> Floor, New York, NY 10119, U.S.A. ("Ophthotech") and Novartis Pharma AG, a Swiss company, with offices at Lichtstrasse 35, CH-4056 Basel, Switzerland ("Novartis").

### **INTRODUCTION**

- 1. Ophthotech is currently developing Fovista (as defined below) for use in combination with anti-VEGF drugs for the treatment of wet age-related macular degeneration ("wet AMD");
- 2. Ophthotech has commenced a pivotal Phase III clinical program to evaluate the safety and efficacy of Fovista administered in combination with anti-VEGF drugs for the treatment of wet AMD;
- 3. Novartis has considerable knowledge and experience in developing, marketing, promoting and selling pharmaceutical products throughout the world;
- 4. Ophthotech desires to enter into an arrangement with respect to the development, marketing, promotion and sale of Fovista outside of the United States; and
- 5. Ophthotech and Novartis believe that an agreement between the companies regarding Fovista and other Products (as defined below) would be desirable.

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, Ophthotech and Novartis hereby agree as follows:

# ARTICLE I DEFINITIONS; INTERPRETATION

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

Section 1.01 "Accounting Standards". Accounting Standards mean, with respect to Ophthotech, U.S. GAAP (United States Generally Accepted Accounting Principles) and, with respect to Novartis, IFRS (International Financial Reporting Standards), in each case, as generally and consistently applied for accounting and financial reporting purposes throughout the Party's organization. Each Party may change the accounting standards that it uses throughout such Party's organization, in which case such Party shall promptly notify the other Party in writing of such change and "Accounting Standards" shall be modified as to such Party accordingly, it being understood that each Party may only use internationally recognized accounting principles (e.g., IFRS, U.S. GAAP, or successor standards thereto).

Section 1.02 "Affiliate". Affiliate means with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" or "controlled" means direct or indirect ownership of fifty percent (50%) or

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more of the shares of stock entitled to vote for the election of directors in the case of a corporation or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity; status as a general partner in any partnership; or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity or the ability to cause the direction of the management or policies of a corporation or other entity. The Parties acknowledge that in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than fifty percent (50%), such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

Section 1.03 "<u>Alternative Anti-PDGF Product</u>". Alternative Anti-PDGF Product means any product that comprises a compound (including any compound that is licensed or acquired from any Third Party) other than Fovista or a Generic/Biosimilar Product as to Fovista, that is Developed in the Field and that binds to and inhibits platelet-derived growth factor (PDGF) or its receptors.

Section 1.04 "API Bulk Drug Substance". API Bulk Drug Substance means Fovista in the pegylated form supplied under the Supply Agreement for use as an active pharmaceutical ingredient in a Product.

- Section 1.05 "Archemix Agreement". Archemix Agreement means the Amended and Restated Exclusive License Agreement, dated as of September 12, 2011, by and between Ophthotech and Archemix Corp., as amended by Amendment No. 1 thereto, dated as of December 20, 2011, as amended from time to time.
- Section 1.06 "<u>Business Day</u>". Business Day means a day that is not a Saturday or Sunday on which banking institutions in both New York, New York and Basel, Switzerland are open for business.
- Section 1.07 "<u>Calendar Quarter</u>". Calendar Quarter means each of the three (3) calendar month periods ending on March 31, June 30, September 30 and December 31 of any Calendar Year; <u>provided that</u> the first Calendar Quarter shall commence on the Effective Date and end on June 30, and, unless otherwise agreed between the Parties, the last Calendar Quarter shall end on the effective date of expiration or termination of the Term.
- Section 1.08 "<u>Calendar Year</u>". Calendar Year means each successive period of twelve (12) months commencing on January 1 and ending on December 31; <u>provided that</u> the first year of the Term shall begin on the Effective Date and end on December 31 of the then current year and the last year of the Term shall begin on the first day of such year and end on the last day of the Term.
- Section 1.09 "<u>Claims</u>". Claims means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

- Section 1.10 "<u>Co-Formulated Product</u>". Co-Formulated Product means a product comprising a formulation of Fovista with a Novartis Anti-VEGF Product, as the sole active pharmaceutical ingredients for administration as a fixed combination.
- Section 1.11 "<u>Co-Packaged Product</u>". Co-Packaged Product means a product in which the Standalone Product and a Novartis Anti-VEGF Product as the sole active pharmaceutical ingredients are packaged together and sold as a single stock keeping unit. The term Co-Packaged Product does not include any Co-Formulated Product.
- Section 1.12 "<u>Collaboration IP</u>". Collaboration IP means, collectively, the Joint Collaboration IP, the Novartis Collaboration IP and the Ophthotech Collaboration IP.
  - Section 1.13 "Combination Product". Combination Product means a Co-Formulated Product or a Co-Packaged Product.
- Section 1.14 "<u>Commercialization</u>" or "<u>Commercialize</u>". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing, exporting, offering to sell or selling a product, including pre-launch activities undertaken in preparation for a product launch, and related Phase IV Clinical Studies. The term Commercialization does not include any activities related to Development or Manufacturing.
- Section 1.15 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means (a) as to Novartis, the expenditure of those efforts and resources used consistent with the usual practice of Novartis and which are consistent with the general standards of comparable companies in the pharmaceutical industry in pursuing development or commercialization for other similar pharmaceutical products with similar market potential and at a similar stage in development, and (b) as to Ophthotech, the expenditure of those efforts and resources used consistent with the usual practice of Ophthotech and which are consistent with the general standards of comparable companies in the biotechnology industry in pursuing development or commercialization for other similar pharmaceutical products with similar market potential and at a similar stage in development.
  - Section 1.16 "Control" or "Controlled". Control or Controlled means:
- (a) with respect to any Intellectual Property right, Trademark or other intangible property, the possession by a Party (whether by license from an Affiliate or a Third Party, ownership, or control over an Affiliate having such possession by license or ownership) of the ability to grant to the other Party access or a license or sublicense as provided herein without violating the terms of any agreement with any Third Party.
- (b) Notwithstanding Section 1.16(a), Ophthotech shall not be considered to Control any Intellectual Property that it licenses from a Third Party if (i) Ophthotech would be required to make any payment in connection with the grant of, or Novartis' exercise of rights under, a sublicense to such Intellectual Property hereunder, and (ii) Novartis does not agree in writing to make any such payment to Ophthotech or its designee. Notwithstanding the foregoing provisions of this subsection (b), Intellectual Property licensed by Ophthotech from Third Parties under the Existing Fovista Agreements that Ophthotech is permitted to sublicense to Novartis as

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provided herein without violating the terms of such Existing Fovista Agreements shall be deemed to be Controlled by Ophthotech and Ophthotech shall be responsible for payments to the applicable Third Party licensors with respect to such Intellectual Property as set forth in Section 7.04(e).

- (c) Notwithstanding Section 1.16(a), Novartis shall not be considered to Control any Intellectual Property that it licenses from a Third Party existing before the Effective Date (or existing as of the Effective Date but not including this Agreement) if (i) Novartis would be required to make any payment in connection with the grant of, or Ophthotech's exercise of rights under, a sublicense to such Intellectual Property hereunder, and (ii) Ophthotech does not agree in writing to make any such payment to Novartis or its designee. Notwithstanding the foregoing provisions of this subsection (c), Intellectual Property relating to ranibizumab licensed by Novartis from Third Parties as of the Effective Date under license agreements other than the Lucentis License Agreement that Novartis is entitled to sublicense to Ophthotech as provided herein without violating the terms of such agreements shall be deemed to be Controlled by Novartis and Ophthotech shall have a royalty-free, fully paid-up sublicense thereunder as set forth in Section 3.04(b).
- Section 1.17 "<u>Cover</u>", "<u>Covering</u>" or "<u>Covered</u>". Cover, Covering or Covered means, with respect to a Patent Right and a Product, that (a) in the case such Patent Right is an issued patent, in the absence of a license granted under an Issued Valid Claim of such Patent Right, the making, use, offering for sale, sale, or importation of the Product in the country of sale would infringe such Issued Valid Claim or (b) in the case such Patent Right is a pending

patent application, that if such Patent Right were to issue as a patent, then, in the absence of a license granted under a Pending Valid Claim of such Patent Right, the making, use, offering for sale, sale, or importation of the Product in the country of sale would infringe such Pending Valid Claim.

- Section 1.18 "<u>Development</u>" or "<u>Develop"</u>. Development or Develop means non-clinical and clinical research and drug development activities, including discovery activities, toxicology, pharmacology and other research and pre-clinical efforts, test method development and stability testing, assay development, process development, formulation development, quality assurance and quality control development, statistical analysis, clinical studies (including pre-approval Investigator Sponsored Clinical Studies), packaging development, regulatory affairs, and the preparation, filing and prosecution of Regulatory Approval and clinical study regulatory activities.
- Section 1.19 "Development Costs". Development Costs means the direct costs incurred by a Party during the Term and pursuant to this Agreement for the Development of a Product, calculated as the sum of (a) Out-of-Pocket Development Expenses, (b) Development FTE Costs and (c) Other Development Expenses, each only to the extent incurred after the Effective Date.
- Section 1.20 "<u>Development FTE Cost</u>". Development FTE Cost means the product of (a) the actual number of FTEs utilized in the Development of a Product in accordance with the Development Plan and associated budget after the Effective Date, as documented by the applicable Party using a reliable time-tracking system and (b) the FTE Rate.

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- Section 1.21 "<u>Development Plan</u>". Development Plan means the plan for the Parties' Development efforts with respect to the Products, as agreed upon by the Parties as of the Effective Date as set forth in <u>Exhibit C</u> hereto, including clinical, regulatory and technical activities, and as updated on an annual basis and as amended from time to time in accordance with the terms of this Agreement.
  - Section 1.22 "EMA". EMA means the European Medicines Agency or any successor agency thereto.
- Section 1.23 "<u>European Union</u>" or "<u>EU</u>". European Union or EU means the countries of the European Union, as it is constituted as of the Effective Date and as its membership may be amended from time to time.
- Section 1.24 "<u>EU Regulatory Approval</u>". EU Regulatory Approval means, with respect to a Product, Regulatory Approval by EMA or national Regulatory Approval from the applicable Regulatory Authority in at least three (3) of the Major European Countries.
- Section 1.25 "Executive Officers". Executive Officers means the Chief Executive Officer of Ophthotech (initially David Guyer) and the Division Head, Pharmaceuticals of Novartis (initially David Epstein).
- Section 1.26 "Existing Fovista Agreements". Existing Fovista Agreements means the Nektar Agreement, the Archemix Agreement, the Novo Agreement and the OSI Agreement.
- Section 1.27 "<u>Existing Fovista Clinical Program</u>". Existing Fovista Clinical Program means the clinical studies of Fovista identified on Exhibit B.
  - Section 1.28 "FDA". FDA means the United States Food and Drug Administration or any successor agency thereto.
- Section 1.29 "FDP". FDP means Novartis' full development point, which is the point at which Novartis decides to proceed with the full development of a product, in accordance with its usual practice as of the Effective Date as consistently applied to products, and any equivalent thereof, without regard to Novartis' nomenclature therefor.
- Section 1.30 "Field". Field means the treatment, prevention, cure or control of any human disease, disorder or condition of the eye. The term Field does not include any diagnostic use.
- Section 1.31 "<u>First Commercial Sale</u>". First Commercial Sale means, with respect to a Product in a country, the first commercial sale of such Product in such country by Novartis, its Affiliates or Sublicensees after all required Regulatory Approval and pricing and reimbursement approval has been granted (if such approval is required). Sales for clinical study purposes or compassionate, named patient or similar use shall not constitute a First Commercial Sale.
- Section 1.32 "<u>Fovista</u>". Fovista means Ophthotech's proprietary anti-PDGF aptamer set forth in <u>Exhibit D</u> attached hereto, in pegylated or unpegylated form.

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- Section 1.33 "FTE". FTE means a full-time equivalent person (*i.e.*, one fully dedicated employee or multiple partially dedicated employees aggregating to one full-time employee employed or contracted by Novartis or Ophthotech) based upon a total of [\*\*] working hours per year, undertaken in connection with the conduct of Development in accordance with the Development Plan or in connection with the Manufacturing activities relating to the selection and management of Third Party manufacturers and the management of such supply.
- Section 1.34 "FTE Rate". FTE Rate means a rate of \$[\*\*] per FTE per annum for Development FTEs and \$[\*\*] per FTE per annum for Manufacturing FTEs during Calendar Year 2014, such amount to be adjusted as of January 1, 2015, and annually thereafter by the percentage increase or decrease, if any, in the Consumer Price Index for All Urban Consumers (CPI-U); U.S. City Average. Such rate shall cover the cost of salaries, benefits, infrastructure costs, travel, general laboratory or office supplies, postage, insurance, training and all other general expenses and overhead items.
- Section 1.35 "<u>Full Royalty Term</u>". Full Royalty Term means, on a Product-by-Product and country-by-country basis, the period beginning on the Effective Date and expiring on the later of the following: (a) expiration of the last-to-expire Valid Claim within the Ophthotech IP or the Ophthotech

Collaboration IP that Covers such Product in such country (where such country is the country of sale); or (b) ten (10) years after First Commercial Sale of such Product in such country.

- Section 1.36 "Generic/Biosimilar Product". Generic/Biosimilar Product means, as to a Product in a country, an anti-PDGF aptamer product (other than a Product or any product authorized or licensed out to a Third Party by Novartis or any of its Affiliates) in the Field that is Commercialized by any Third Party and that:
  - (a) has the same product profile as the applicable Product, and
- (b) is generic, biosimilar or bioequivalent to and approved pursuant to an abbreviated regulatory process based on the clinical data for the applicable Product and studies showing that such product is biosimilar or bioequivalent to such Product.
- Section 1.37 "<u>Good Clinical Practice</u>". Good Clinical Practice means the current good clinical practice applicable to the clinical Development of pharmaceutical products under applicable Law, to the extent such standards are not less stringent than the U.S. current good clinical practice.
- Section 1.38 "Good Laboratory Practice". Good Laboratory Practice means the current good laboratory practice applicable to the Development of pharmaceutical products under applicable Law, to the extent such standards are not less stringent than the U.S. current good laboratory practice, including 21 C.F.R. Part 58.
- Section 1.39 "<u>Good Manufacturing Practice</u>". Good Manufacturing Practice means the current good manufacturing practice regulations as set out in the European Commission Directive 2003/94/EC of 8th October 2003 (as amended) and 21 C.F.R. Sections 210, 211 and 600, stating the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

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- Section 1.40 "Governmental Authority". Governmental Authority means any federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- Section 1.41 "<u>Government Order</u>". Government Order means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority.
- Section 1.42 "<u>Handle</u>" or "<u>Handling</u>". Handle or Handling means, with respect to a Patent Right, to prepare, file, prosecute, maintain or defend such Patent Right. For clarity, Handling does not include initiating any claim or action to enforce Patent Rights against actual or alleged infringers.
- Section 1.43 "Insolvency Event". Insolvency Event means, in relation to either Party, any one of the following: (a) that Party becomes insolvent; (b) that Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings which are dismissed within sixty (60) days); (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party; (d) a notice shall have been issued to convene a meeting for the purpose of passing a resolution to wind up that Party, or such a resolution shall have been passed other than a resolution for the solvent reconstruction or reorganization of that Party; (e) a resolution shall have been passed by that Party or that Party's directors to make an application for an administration order or to appoint an administrator; or (f) that Party proposes or makes any general assignment, composition or arrangement with or for the benefit of all or some of that Party's creditors or makes or suspends or threatens to suspend making payments to all or some of that Party's creditors.
- Section 1.44 "<u>Intellectual Property</u>". Intellectual Property means Patent Rights, utility models, registered designs, unregistered design rights, registered and unregistered copyrights, Know-How, Confidential Information, database rights, any rights in clinical study results, applications for and the right to apply for any such rights, and any similar or analogous rights anywhere worldwide. Intellectual Property does not include Trademarks.
- Section 1.45 "<u>Investigator Sponsored Clinical Study</u>". Investigator Sponsored Clinical Study means a human clinical study of a Product that is sponsored and conducted by a Third Party under an agreement with a Party pursuant to which such Party provides clinical supplies of the Product or funding for such clinical study.
- Section 1.46 "Know-How". Know-How means any information or material, whether proprietary or not and whether patentable or not, including ideas, concepts, formulas, methods, procedures, designs, compositions, plans, documents, data, trade secrets, inventions, discoveries, works of authorship, compounds and biological materials.

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- Section 1.47 "<u>Law</u>". Law means all laws, statutes, rules, regulations, orders, judgments, injunctions or ordinances of any Governmental Authority.
- Section 1.48 "Loss of Market Exclusivity". Loss of Market Exclusivity means, for a Product on a country-by-country and Calendar Year-by-Calendar Year basis, the following has occurred: (a) the Net Sales of such Product in such country in such Calendar Year are less than [\*\*] percent ([\*\*]%) of the peak annual Net Sales of such Product in such country in any preceding Calendar Year, and (b) the decline in such Net Sales is attributable in material part to the marketing or sale by a Third Party in such country of a Generic/Biosimilar Product with respect to such Product.
  - Section 1.49 "Major European Country". Major European Country means any of the United Kingdom, France, Germany, Italy or Spain.
- Section 1.50 "<u>Manufacturing</u>" or "<u>Manufacturing</u>". Manufacturing or Manufacture means activities directed to producing, manufacturing, processing, sourcing of materials, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

"Manufacturing Cost". Manufacturing Cost means, with respect to any material supplied by a Party hereunder, the standard unit Section 1.51 cost of Manufacture of such material, consisting of direct material and direct labor costs plus Manufacturing overhead attributable to such material (including all directly incurred manufacturing variances), all calculated in accordance with such Party's Accounting Standards and internal cost accounting procedures, consistently applied. Direct material costs will include the costs incurred in Manufacturing or purchasing materials for use in Manufacturing such material, including freight in costs, sales and excise taxes imposed thereon and customs duty and charges levied by Governmental Authorities, and all costs of packaging components. Direct labor costs will include the costs of employees engaged in direct Manufacturing activities and direct or indirect quality control and quality assurance activities who are directly employed in Manufacturing and packaging such material. Overhead attributable to such material will be calculated and allocated in a manner consistent with the method used to allocate overhead to other material Manufactured in the same facility. Overhead attributable to such material will include a reasonable allocation of indirect labor (not previously included in direct labor costs), a reasonable allocation of administrative costs, and a reasonable allocation of facilities costs, all in accordance with such Party's Accounting Standards and internal cost accounting procedures, consistently applied. Overhead will not include corporate administrative overhead or plant start-up costs or costs associated with excess or idle capacity. Alternatively, if such material is Manufactured by a Third Party manufacturer, the Manufacturing Cost means the actual price paid by such Party or its Affiliates to the Third Party for the Manufacture, supply and packaging of such material, and all taxes and shipping costs related thereto, including any license or royalty fees (other than license or royalty fees payable pursuant to the Existing Fovista Agreements) and the cost of any materials supplied and paid for by such Party and reasonable and necessary FTE costs (calculated at the FTE Rate) of such Party's or its Affiliates' employees engaged in activities relating to the selection and management of such Third Party manufacturer and the management of such supply (including quality control and quality assistance activities).

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Section 1.52 "[\*\*].

Section 1.53 "Nektar Agreement". Nektar Agreement means the License, Manufacturing and Supply Agreement, dated as of September 30, 2006, by and between Nektar Therapeutics AL, Corporation and (OSI) Eyetech, Inc., as the same was assigned to Ophthotech on July 27, 2007 and amended by Amendment No. 1 thereto, dated as of April 5, 2012, and supplemented by a letter agreement, dated as of June 20, 2013, as amended from time to time.

- Section 1.54 "Net Sales". Net Sales means, with respect to a Product, the gross sales recorded by Novartis or any of its Affiliates or Sublicensees for the Product sold to Third Parties other than Sublicensees, less deductions actually taken or applied, in the case of both gross sales and deductions as determined in accordance with the Accounting Standards as consistently applied across its products generally, which deductions include the following:
  - (a) normal trade and cash discounts;
  - (b) amounts repaid or credited by reasons of defects, rejections, recalls or returns;
- (c) rebates and chargebacks to customers and Third Parties (including Medicare, Medicaid, Managed Healthcare and similar types of rebates);
  - (d) amounts provided or credited to customers through coupons and other discount programs;
- (e) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates and retroactive price reductions;
- (f) compensation paid to non-Affiliate distributors and wholesalers for maintaining agreed inventory levels and providing information;
- (g) other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with the Accounting Standards.

Such deductions shall be booked on an accrual basis by Novartis, its Affiliates and Sublicensees under the Accounting Standards to calculate the recorded net sales from gross sales. Such net sales will be reduced by an additional [\*\*] percent ([\*\*]%) of such net sales for the direct expenses related to the sales of the Product, distribution and warehousing expenses and uncollectible amounts on previously sold Products.

With respect to the calculation of Net Sales:

- (x) Net Sales only include the value charged or invoiced on the first arm's-length sale to a Third Party and sales between or among Novartis and its Affiliates and Sublicensees will be disregarded for purposes of calculating Net Sales; and
- (y) if a Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition

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criteria under the Accounting Standards are met, or when payment is received, whichever is earlier.

Section 1.55 "Novartis Anti-VEGF Product". Novartis Anti-VEGF Product means Lucentis® (ranibizumab), RTH258 (formerly ESBA1008) as set forth in Exhibit E attached hereto, or any other anti-VEGF product in the Field that is Controlled by Novartis or any of its Affiliates as may be agreed to be included in the future under the terms of this Agreement in writing by the Parties, in each case regardless of finished form, formulation, preparation, packaging or dosing.

Section 1.56 "Novartis IP". Novartis IP means the Intellectual Property relating to the Novartis Anti-VEGF Products and the Pre-Filled Syringe that is Controlled by Novartis as of the Effective Date or thereafter during the Term, that is reasonably necessary or useful for the Development, Manufacture

- or Commercialization of a Product in the Field. The term Novartis IP shall not include the Novartis Collaboration IP or Novartis' rights in the Joint Collaboration IP.
  - Section 1.57 "Novartis Territory". Novartis Territory means the entire world, excluding the Ophthotech Territory.
- Section 1.58 "Novo Agreement". Novo Agreement means the Purchase and Sale Agreement, dated as of May 23, 2013, by and between Ophthotech and Novo A/S, as amended from time to time.
- Section 1.59 "Ophthotech Anti-VEGF Product". Ophthotech Anti-VEGF Product means a product Controlled by Ophthotech or any of its Affiliates comprising an anti-VEGF compound as the sole active pharmaceutical ingredient, excluding a Novartis Anti-VEGF Product.
- Section 1.60 "Ophthotech Change in Control". Ophthotech Change in Control means any transaction or series of related transactions in which a Third Party (or group of Third Parties acting in concert) (a) acquires or becomes the beneficial owner of more than fifty percent (50%) of the outstanding voting securities of Ophthotech, (b) becomes the surviving entity in any merger, consolidation, reorganization, tender offer or similar transaction to which Ophthotech is a party, or as a result of which more than fifty percent (50%) of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the Persons holding at least fifty percent (50%) of the outstanding shares of Ophthotech preceding such transaction, or (c) acquires or otherwise receives the benefit of all or substantially all of the assets of Ophthotech, including the rights to Fovista for the Ophthotech Territory.
- Section 1.61 "Ophthotech IP". Ophthotech IP means the Intellectual Property relating to Fovista that is Controlled by Ophthotech as of the Effective Date, including the Patent Rights set out in Exhibit A attached hereto and updated on an annual basis (the "Ophthotech Product Patent Rights"), or thereafter during the Term, that is reasonably necessary or useful for the Development, Manufacture or Commercialization of a Product in the Field. The term Ophthotech IP shall not include the Ophthotech Collaboration IP or Ophthotech's rights in the Joint Collaboration IP.

- Section 1.62 "Ophthotech Territory". Ophthotech Territory means the United States.
- Section 1.63 "OSI Agreement". OSI Agreement means the Divestiture Agreement, dated as of July 27, 2007, by and between Ophthotech and (OSI) Eyetech, Inc., as amended from time to time
- Section 1.64 "Other Development Expenses". Other Development Expenses means any Development expenses incurred for clinical materials, analytical services or other items specifically agreed upon to the extent not included in Out-of-Pocket Development Expenses and are not items covered by the Development FTE Cost.
- Section 1.65 "Out-of-Pocket Development Expenses". Out-of-Pocket Development Expenses means direct expenses paid or payable to Third Parties which are specifically identifiable and incurred by a Party for the Development activities of a Product, provided that such expenses will have been recorded as income statement items in accordance with such Party's Accounting Standards and will not include any pre-paid amounts, capital expenditures, or items covered by the Development FTE Cost.
  - Section 1.66 "Parties". Parties means Ophthotech and Novartis.
  - Section 1.67 "Party". Party means either Ophthotech or Novartis.
- Section 1.68 "<u>Patent Rights</u>". Patent Rights means patents and patent applications, and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions (including supplemental protection certificates) thereof, and all counterparts thereof in any country.
- Section 1.69 "<u>Person</u>". Person means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
- Section 1.70 "<u>Phase I Clinical Study</u>". Phase I Clinical Study means a clinical study of a product in human volunteers or patients with the endpoint of determining initial tolerance, toxicity, safety or pharmacokinetic information, as described in 21 C.F.R. 312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
- Section 1.71 "Phase II Clinical Study". Phase II Clinical Study means a preliminary efficacy and safety or dose-ranging human clinical study of a product in the target patient population, as described in 21 C.F.R. 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States, which shall be deemed commenced when the first patient in such study has received his or her initial dose of a product.
- Section 1.72 "<u>Phase III Clinical Study</u>". Phase III Clinical Study means a human clinical study to confirm with statistical significance the efficacy and safety of a product performed to obtain Regulatory Approval for a product in any country, as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority

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in a country other than the United States, which shall be deemed commenced when the first patient in such study has received his or her initial dose of a product.

Section 1.73 "Phase IV Clinical Study". Phase IV Clinical Study means a human clinical study that is conducted post Regulatory Approval and that is not for the purpose of (a) obtaining, maintaining or expanding a Regulatory Approval, or (b) studying the applicable Product for a potential expanded label

- Section 1.74 "<u>Pre-Filled Syringe</u>". Pre-Filled Syringe means a pre-filled syringe containing Fovista and Developed by Novartis hereunder in accordance with the Development Plan, for use as the Standalone Product, in a Co-Packaged Product, or as the Co-Formulated Product.
- Section 1.75 "<u>Product</u>". Product means, as applicable, the Standalone Product, a Co-Packaged Product or a Co-Formulated Product, whether contained in a vial, a Pre-Filled Syringe or any other agreed container, or any other product that the Parties may agree in writing to be subject to this Agreement. The term Product shall not include API Bulk Drug Substance to the extent it is not incorporated into a Product.
- Section 1.76 "Product Trademark". Product Trademark means the "Fovista" Trademark and any other Trademark that is proposed by the JCS as part of the Product Positioning and Branding Strategy and approved by the JOC for use in connection with the Commercialization of Products in the Novartis Territory and subject to any Third Party rights in the relevant Trademarks. The term Product Trademark shall not include any Trademark relating to, consisting of, or containing "Lucentis" or the corporate names or logos of either Party.
- Section 1.77 "<u>Reduced Royalty Term</u>". Reduced Royalty Term means the period beginning on the expiration of the Full Royalty Term for a Product in a country and expiring upon Novartis' actual last commercial sale of such Product in such country.
- Section 1.78 "Regulatory Approval". Regulatory Approval means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in a country, excluding separate pricing or reimbursement approvals that may be required.
- Section 1.79 "<u>Regulatory Authority</u>". Regulatory Authority means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country.
- Section 1.80 "Related Agreements". Related Agreements means any additional agreements that the Parties enter into relating to this Agreement, including the Supply Agreement (for API Bulk Drug Substance), the related quality agreement, the pharmacovigilance agreement for the Products, any supply agreement for the Pre-Filled Syringe, any supply agreement for the Co-Formulated Product, and any agreement entered into between the Parties pursuant to Section 3.01(f), Section 3.04(c), Section 3.04(f), Section 3.05(e), Section 3.07(g)(ii) or Section 5.09.

- Section 1.81 "SDP". SDP means Novartis' submission decision point, which is the point at which Novartis decides to submit an application for Regulatory Approval of a product, in accordance with its usual practice as of the Effective Date as consistently applied to products, and any equivalent thereof, without regarding to Novartis' nomenclature therefor.
- Section 1.82 "<u>Standalone Product</u>". Standalone Product means a product comprising Fovista as the sole active pharmaceutical ingredient, formulated for use as a single dose.
- Section 1.83 "Standalone Product Net Price". Standalone Product Net Price means, with respect to a Combination Product in a country for a given Calendar Year, the aggregate Net Sales of the Standalone Product in such country (or, if the Standalone Product is not sold in such country, the aggregate Net Sales of the Standalone Product in the three (3) other countries in which it and the relevant Combination Product are sold where the price for such Combination Product is most comparable to the price for such Combination Product in the relevant country) during the prior Calendar Year divided by the number of units of Standalone Product generating such Net Sales during such period. In the event there is a country in the Novartis Territory where the Standalone Product is not launched but a Combination Product will be launched, the JOC will pre-agree at the time of launch of the Combination Product in such country the three (3) reference countries described that will be applicable for purposes of this definition.
- Section 1.84 "<u>Subcommittees</u>". Subcommittees means the Joint Clinical Development/Regulatory Subcommittee, the Joint Manufacturing/Technical Development Subcommittee, the Joint Commercialization Subcommittee and any other committee established by and under the governance of the JOC.
- Section 1.85 "Sublicensee". Sublicensee means any Person to which a Party grants a sublicense of any right granted to such Party hereunder, excluding Third Party distributors and Third Party wholesalers.
  - Section 1.86 "Third Party". Third Party means any Person other than a Party or any of its Affiliates.
- Section 1.87 "<u>Third Party IP</u>". Third Party IP means Intellectual Property owned or controlled by any Third Party relating to the subject matter of this Agreement as of the Effective Date or thereafter during the Term.
- Section 1.88 "<u>Trademark</u>". Trademark means any and all trademarks of every kind and nature, however designated, whether arising by operation of law, contract, license or otherwise, whether or not registered or unregistered, including product names, trade names, service marks, logos, program names, taglines, slogans, trade dress, and any other indicia of origin, including all related rights thereto, such as copyrights and design rights (including design patents rights) in pictures, logos, icons, drawings and the like, and any similar or analogous rights anywhere worldwide.
  - Section 1.89 "United States" or "U.S.". United States or U.S. means the United States of America and its territories and possessions.

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- Section 1.90 "Valid Claim". Valid Claim means, with respect to any country, (a) a claim of an issued and unexpired patent (an "Issued Valid Claim") or (b) a claim in a filed but not yet granted patent application that has not been pending for longer than [\*\*] years following the filing of the earliest application from which such patent application derives priority (a "Pending Valid Claim"), in each case where such claim has not been: (w) disclaimed, cancelled, withdrawn or abandoned, (x) dedicated to the public, (y) declared invalid, unenforceable, unpatentable or revoked by a decision of a court, government agency or other authority of competent jurisdiction from which no appeal can be or has been taken, or (z) admitted to be invalid or unenforceable through reexamination, reissue or otherwise.
  - Section 1.91 <u>Additional Definitions</u>. The definition of each of the following terms is set forth in the Section of this Agreement indicated below:

<u>Term</u>	Section
13D Group	Section 10.08(a)(ii)
1974 Convention	Section 13.01
Agreement	Preamble
API Supply	Section 6.03
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Ophthotech Collaboration IP	Section 8.01(b)(iii)
Ophthotech Indemnified Parties	Section 10.10(b)
Ophthotech Patent Rights	Section 8.02(b)
Ophthotech Product Patent Rights	Section 1.61
[**]	Section [**]
OSI IP	Section 3.01(i)
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Section 1.92 <u>Interpretation</u>. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall." The headings contained in this Agreement or any Exhibit and in the table of contents to this Agreement are for reference purposes only and

particular provision hereof; (c) the word "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends and such phrase does not mean simply "if"; (d) the word "or" shall be inclusive and not exclusive (i.e., "and/or"); and (e) all references herein to ARTICLES, Sections or Exhibits shall be construed to refer to ARTICLES, Sections and Exhibits of this Agreement. All Exhibits attached hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in the Exhibits attached hereto but not otherwise defined therein shall have the meaning as defined in this Agreement. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any provision of this Agreement.

### ARTICLE II GOVERNANCE

### Section 2.01 <u>Joint Operating Committee</u>.

- (a) Formation; Purposes and Principles. Within [\*\*] days after the Effective Date, Ophthotech and Novartis shall establish a Joint Operating Committee (the "JOC"), which shall have overall responsibility for the operations and strategy of the collaboration established by this Agreement. The purposes of the JOC shall be (i) to annually review and approve the Development (other than with respect to the Existing Fovista Clinical Program), Manufacture (other than with respect to the Existing Fovista Clinical Program and without modifying the Parties' respective rights and obligations under the Supply Agreement) and Commercialization strategy for the Products in the Novartis Territory, (ii) discussion of, but not decision-making authority over, other aspects of Ophthotech's Development, Manufacturing and Commercialization activities in the Ophthotech Territory that are relevant to Products in the Novartis Territory, (iii) to oversee the Subcommittees and resolve matters within the authority of the Subcommittees on which any Subcommittee is unable to reach consensus, and (iv) to oversee the Parties' operational Development, Manufacturing and Commercialization activities for Products in the Novartis Territory pursuant to the collaboration.
- (b) Membership. The JOC shall be composed of [\*\*] representatives appointed by each of Ophthotech and Novartis who are within management of each Party and who have sufficient authority, relevant knowledge and expertise in the Development, Manufacturing and Commercialization of pharmaceutical products. The initial members of the JOC from each Party shall be selected and identified to the other Party within [\*\*] days after the Effective Date or such later date as the Parties may agree. Each Party may replace any of its JOC representatives at any time upon written notice to the other Party.
- (c) <u>Specific Responsibilities</u>. In addition to its overall responsibility for the collaboration established by this Agreement, the JOC shall in particular:
- (i) review the general strategy for pricing and reimbursement approval and general strategy for discounting of the Products in the Novartis Territory;

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- (ii) review and approve the Product positioning and branding strategy for the Novartis Territory, including the Product Trademarks (the "Product Positioning and Branding Strategy");
- (iii) annually review and approve the Development Plan, substantive updates or amendments thereof, and the budget for jointly funded Development activities;
- (iv) agree on the scope, extent and detail to be included in the Initial Marketing Plan, which shall be consistent with Exhibit F and Section 5.04 hereto, and approve the Initial Marketing Plan and each subsequent annual Marketing Plan to ensure effective Commercialization of the Products in the Novartis Territory;
- (v) seek to reach consensus regarding reference countries to be used, if applicable, for the calculation of the Standalone Product Net Price in accordance with the definition thereof, provided that, in the absence of consensus, such matters shall not be Ophthotech Casting Vote Matters or Novartis Casting Vote Matters and shall be resolved in accordance with Section 2.08(d); and
  - (vi) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

#### Section 2.02 <u>Joint Clinical Development/Regulatory Subcommittee</u>.

- (a) <u>Formation; Purposes</u>. Within [\*\*] days after the Effective Date, Ophthotech and Novartis shall establish a joint clinical development/regulatory subcommittee (the "JCD/RS") of the JOC, which shall have responsibility for overseeing the implementation of all operational Development (including regulatory) aspects of the collaboration established by this Agreement.
  - (b) <u>Specific Responsibilities</u>. In particular, the JCD/RS shall:
- (i) develop in collaboration with the other appropriate Subcommittees and propose to the JOC the integrated strategy for the Development of the Products for the Novartis Territory (except with respect to the Existing Fovista Clinical Program) taking into account Ophthotech's development strategy for the Ophthotech Territory;

- (ii) prepare and present to the JOC for its review and approval annual updates to the Development Plan and, as to joint Development activities, the budget therefor and, from time to time, propose substantive amendments to the Development Plan and such budgets in accordance with Section 4.03;
- (iii) oversee the implementation of the initial Development Plan attached hereto as <u>Exhibit C</u> and, following JOC approval, any updated Development Plan;
- (iv) coordinate the publication strategy for Products (excluding Ophthotech's publication strategy for the Existing Fovista Clinical Program and other research and development activities of Ophthotech prior to the first EU Regulatory Approval of the Standalone Product, as to which Ophthotech shall inform the JCD/RS); and

- (v) coordinate activities between the Parties for regulatory matters with respect to the Novartis Territory, subject to the responsibilities that are expressly allocated to a Party under the terms of this Agreement
- Section 2.03 <u>Joint Manufacturing/Technical Development Subcommittee</u>. Within [\*\*] days after the Effective Date, Ophthotech and Novartis shall establish a joint manufacturing/technical development subcommittee (the "JMS") of the JOC, which shall, subject to the Parties' respective rights and obligations under the Supply Agreement, have responsibility for advising the Parties on, but which shall not have any decision-making authority over, the implementation of operational Manufacturing and related technical development aspects of the collaboration established by this Agreement, including the Manufacture and supply of API Bulk Drug Substance, relevant technical development activities, setting of relevant specifications, Manufacturing validation strategy, monitoring of corrective and preventative action (CAPA) plans for API Bulk Drug Substance manufacturing site and manufacturing site for clinical supplies for the Existing Fovista Clinical Program, Manufacturing improvements, supply allocation, business continuity measures for Manufacturing, plans for changes in Manufacturing required by regulatory mandates, and sourcing of critical materials. Ophthotech shall update the JMS from time to time regarding Manufacturing Costs for the API Bulk Drug Substance and Novartis shall update the JMS from time to time regarding Manufacturing Costs for materials Novartis supplies to Ophthotech pursuant to any supply agreement entered into in accordance with this Agreement.

#### Section 2.04 Joint Commercialization Subcommittee.

- (a) <u>Formation; Purposes</u>. Within [\*\*] days after the Effective Date, Ophthotech and Novartis shall establish a joint commercialization subcommittee (the "JCS") of the JOC, which shall have responsibility for overseeing the Commercialization strategy of the collaboration established by this Agreement, taking into account Ophthotech's Commercialization strategy for the Ophthotech Territory.
  - (b) <u>Specific Responsibilities</u>. In particular, the JCS shall:
    - (i) develop and propose to the JOC the Product Positioning and Branding Strategy;
- (ii) establish and propose to the JOC the general strategy for pricing and reimbursement approval and general strategy for discounting of the Products in the Novartis Territory;
- (iii) annually review, update and approve the Marketing Plan and from time to time present to the JOC for its review and approval proposed substantive amendments to the Marketing Plan in accordance with Section 5.04;
- (iv) coordinate the communication strategy for Products (excluding Ophthotech's publication strategy for the Existing Fovista Clinical Program and other research and development activities of Ophthotech prior to the first EU Regulatory Approval of the Standalone Product, as to which Ophthotech shall inform the JCS); and

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- (v) determine and propose to the JOC the reference countries to be used for the calculation of the Standalone Product Net Price in accordance with the definition thereof.
- Section 2.05 <u>Chairpersons</u>. The JOC and each of the Subcommittees shall have co-chairpersons, one (1) appointed by each of Ophthotech and Novartis (the "Co-Chairs"). The Co-Chairs shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [\*\*] days thereafter.
- Section 2.06 <u>Working Groups</u>. From time to time, each Subcommittee may establish one or more working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the establishing Subcommittee determines.
- Section 2.07 <u>Subcommittee Membership</u>. Each of the Subcommittees shall be composed of representatives appointed by each of Ophthotech and Novartis. The Subcommittees shall each initially have not less than [\*\*], and not more than [\*\*], representatives of each Party, but the JOC may change the size of any Subcommittee from time to time by mutual consent of the members of the JOC. Each Party may replace its Subcommittee and Working Group representatives at any time upon written notice to the other Party.

### Section 2.08 <u>Decision-Making</u>.

(a) All decisions of each Subcommittee shall be made by consensus of the applicable Co-Chairs or their designees. All decisions of each Working Group shall be made by consensus of its members, with the representatives of each Party having collectively one (1) vote on behalf of such Party. Should the members of a Working Group or a Subcommittee disagree on any matter for which consensus has been sought and Ophthotech or Novartis requests a resolution, the matter shall be referred to the applicable Subcommittee in the case of a Working Group, and to the JOC in the case of the Subcommittees, for resolution.

- (b) All decisions of the JOC shall be made by consensus of the Co-Chairs. Should the Co-Chairs disagree on any matter within the authority of the JOC, either Party may issue a notice to the other requiring that the Co-Chairs attempt in good faith to agree on the matter by consensus. If the Co-Chairs are unable to reach a decision by consensus within [\*\*] Business Days of such notice then the matter will be resolved as set forth in subsections (c) and (d) below, as applicable.
- (c) If any matter within the authority of the JOC and as to which the JOC and Co-Chairs fail to reach consensus pursuant to subsections (a) and (b) above arises, then
  - (i) with respect to the following issues, the Ophthotech Co-Chair shall have decision-making authority:
- A. the Existing Fovista Clinical Program, including regulatory matters and filing of applications for, and seeking of, EU Regulatory Approval for the Standalone Product, including decisions concerning the initial labelling of the Standalone Product based on the Existing Fovista Clinical Program; provided that Novartis shall be

responsible for post-approval commitments related to EU Regulatory Approval and Ophthotech shall not have final decision-making authority with respect thereto:

- B. the API Supply (excluding any areas expressly stated in the Supply Agreement or any Related Agreements addressing quality requirements for the API Supply); and
- C. the design and conduct of any study undertaken in the Development of a Product that is initiated prior to the first EU Regulatory Approval of the Standalone Product as to which Ophthotech has *bona fide* scientific or safety concerns or concerns relating to consistency with Ophthotech's global Development strategy for Fovista,

(A-C together, "Ophthotech Casting Vote Matters"), and the Ophthotech Co-Chair shall provide Novartis with prompt notice in writing of such decision; and

(ii) the Novartis Co-Chair shall have decision-making authority with respect to all matters within the authority of the JOC other than those set forth in Section 2.08(c)(i) above solely relating to Novartis' Development (including regulatory), Manufacturing and Commercialization activities under this Agreement with respect to Products for the Novartis Territory (such matters together, "Novartis Casting Vote Matters"), and the Novartis Co-Chair shall provide Ophthotech with prompt notice in writing of such decision.

Notwithstanding anything in the foregoing provisions of this Section 2.08(c) to the contrary, neither Party (nor its Co-Chair) shall have final decision-making authority pursuant to this Section 2.08(c) with respect to the following matters, and such matters shall not constitute Ophthotech Casting Vote Matters or Novartis Casting Vote Matters: (1) Legal Disputes, (2) matters over which the other of the Parties is expressly allocated control or decision-making authority elsewhere in this Agreement and as to such matters, the Party so allocated control or decision-making authority elsewhere in this Agreement shall have such control or decision-making authority), (3) matters as to which this Agreement provides that a decision shall not be made without the agreement, approval or consent of one or both of the Parties, or (4) matters that otherwise modify the terms and conditions of this Agreement or any Related Agreement or any Related Agreement, or increase the other Party's obligations or reduce the other Party's rights under the express terms of this Agreement or any Related Agreement.

(d) If the JOC cannot resolve any matter within the authority of the JOC which is not an Ophthotech Casting Vote Matter or a Novartis Casting Vote Matter (each, a "Non-Casting Vote Matter"), then either Party may refer the matter to the Executive Officers for resolution. If after discussing the Non-Casting Vote Matter in good faith and attempting to find a mutually satisfactory resolution to the issue, the Executive Officers fail to come to consensus within [\*\*] Business Days after the date on which the Non-Casting Vote Matter is referred to the Executive Officers (unless a longer period is agreed to in writing by the Executive Officers), then, to the extent such Non-Casting Vote Matter is susceptible of resolution through binding arbitration, such Non-Casting Vote Matter shall, at the request of either Party, be resolved through binding arbitration under Section 12.02.

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Section 2.09 Meetings of the JOC, Subcommittees and Working Groups. Each of the JOC, the Subcommittees and the Working Groups shall hold meetings at such times as the Parties shall determine, but in no event shall such meetings of the JOC and the Subcommittees be held less frequently than [\*\*] during the Term. The JOC shall conduct [\*\*] such meetings [\*\*] in locations to be agreed upon by the Co-Chairs, at least one of which shall be held at a mutually agreed location in [\*\*]. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of the Product may attend meetings of the JOC, Subcommittees or Working Group as nonvoting observers with the consent of each Party. Meetings of the JOC, Subcommittees or Working Groups may be held in person, by audio or video teleconference, as may be agreed by the Co-Chairs of the JOC, the Co-Chairs of the relevant Subcommittee or the Co-Chairs of the Subcommittee that established the relevant Working Group, as the case may be. Each Party shall be responsible for all of its own expenses of participating in the JOC, Subcommittees and Working Groups. No action taken at a meeting of the JOC or a Subcommittee shall be effective unless each Co-Chair (or, as to a Subcommittee, the Co-Chair's designee (as permitted in Section 2.08(a))) is present or participating, and no action taken at a meeting of a Working Group shall be effective unless a representative of each Party is present or participating.

Section 2.10 Alliance Managers. Each Party shall designate a single alliance manager for all of the activities contemplated under this Agreement. Such alliance managers will be responsible for the day-to-day worldwide coordination of the collaboration contemplated by this Agreement and will serve to facilitate communication between the Parties. Such alliance managers shall have sufficient seniority, experience and knowledge appropriate for managers with such project management responsibilities. Each Party may change its designated alliance manager from time to time upon notice to the other Party.

Section 2.11 <u>Discontinuation of Participation on a Committee</u>. Without limiting Section 11.09, with respect to the JOC, each of the Subcommittees and each of the Working Groups shall continue to exist until the first to occur of (a) in the case of the JOC and each Subcommittee, the Parties mutually agreeing to disband such committee, (b) in the case of a Working Group, the Subcommittee forming such Working Group determining to disband such Working Group, or (c) Ophthotech providing Novartis with written notice of its intention to disband and no longer participate in such committee or Working Group; provided that, Ophthotech may only exercise such right to disband a committee or Working Group following the [\*\*] anniversary of EU Regulatory Approval of the Standalone Product. After the JOC, a Subcommittee or a Working Group is disbanded under this Section 2.11, any decision previously within the purview of such committee or Working Group shall be made directly between the Parties and the provisions of Sections 2.08(c) and 2.08(d) shall apply to such decisions between the Parties as if such matters had been first considered by the JOC. In addition, after the JOC is disbanded under this Section 2.11, either Party may change its designated Executive Officer, and Ophthotech may request, and Novartis shall provide Ophthotech, within [\*\*] days after such request, not more frequently than [\*\*], a reasonably detailed written update with respect to Novartis' activities related to the Development and Commercialization of Product(s) with the Parties to mutually agree on the reasonable scope of information to be included therein. Ophthotech shall have the opportunity to reasonably seek further explanation or clarification of material matters related to such Development and Commercialization, and Novartis shall use Commercially Reasonable Efforts to provide such explanation or clarification. In addition, at

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any time when Ophthotech, its Affiliates or any Person that acquired Ophthotech in an Ophthotech Change in Control has filed for Regulatory Approval in the Novartis Territory or is Commercializing in the Novartis Territory an Ophthotech Anti-VEGF Product, and has not terminated all Development and Commercialization of such Ophthotech Anti-VEGF Product in the Novartis Territory, the JOC, each Subcommittee and each Working Group shall limit the scope of their oversight of the Parties' collaboration hereunder to exclude discussions, decision-making or other oversight over matters relating to products comprising or consisting of anti-VEGF products; provided that the Parties shall consult and coordinate with one another to the extent reasonably necessary to preserve the value of the Products in the Parties' respective territories on matters such as pharmacovigilance and Manufacturing and that in no event Novartis shall have any obligation to provide information related to anti-VEGF products in the Ophthotech Territory.

### ARTICLE III LICENSES; OPTIONS; OTHER RIGHTS

### Section 3.01 Grants by Ophthotech.

- (a) <u>Development License</u>. Subject to the terms and conditions of this Agreement, including Ophthotech's exclusive right to conduct the Existing Fovista Clinical Program and Ophthotech's right to conduct other Development activities in the Novartis Territory as set forth in Section 4.08(a), Ophthotech hereby grants to Novartis an exclusive right and license, with right to grant sublicenses as set forth in Section 3.01(f), under the Ophthotech IP, the Ophthotech Collaboration IP, and Ophthotech's rights in the Joint Collaboration IP, to Develop or have Developed Products in the Field for the Novartis Territory; for clarity, rights to any study data Controlled by Ophthotech shall be subject to Section 3.01(d) below. Except for any technology within the Ophthotech Collaboration IP and Ophthotech's rights in the Joint Collaboration IP, the license set forth in this Section 3.01(a) excludes all rights to any technology not Controlled by Ophthotech as of the Effective Date and such license shall not require Ophthotech to conduct any technology transfer or provide access to such excluded technology.
- (b) <u>Commercialization License</u>. Subject to the terms and conditions of this Agreement, Ophthotech hereby grants to Novartis an exclusive right and license, with the right to grant sublicenses as set forth in Section 3.01(f), under the Ophthotech IP, the Ophthotech Collaboration IP, and Ophthotech's rights in the Joint Collaboration IP, to Commercialize and, pursuant to sublicenses granted in accordance with Section 3.01(f), have Commercialized Products in the Field in the Novartis Territory. Except for any technology within the Ophthotech Collaboration IP and Ophthotech's rights in the Joint Collaboration IP, the license set forth in this Section 3.01(b) excludes all rights to any technology not Controlled by Ophthotech as of the Effective Date and such license shall not require Ophthotech to conduct any technology transfer or provide access to such excluded technology. For clarity, Ophthotech shall be restricted from Commercializing any product comprising Fovista in the Novartis Territory except as otherwise expressly specified in the Agreement.
- (c) <u>Manufacturing License</u>. Subject to the terms and conditions of this Agreement, including Ophthotech's exclusive right to Manufacture or have Manufactured API Supply as set forth in Section 6.03, Ophthotech hereby grants to Novartis an exclusive,

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worldwide right and license, with the right to grant sublicenses as set forth in Section 3.01(f), under the Ophthotech IP, the Ophthotech Collaboration IP, and Ophthotech's rights in the Joint Collaboration IP, to Manufacture Products from API Bulk Drug Substance supplied to Novartis by Ophthotech, for Development and Commercialization of Products in the Field for the Novartis Territory. Except for any technology within the Ophthotech Collaboration IP and Ophthotech's rights in the Joint Collaboration IP, the license set forth in this Section 3.01(c) excludes all rights to any technology not Controlled by Ophthotech as of the Effective Date and such license shall not require Ophthotech to conduct any technology transfer or provide access to such excluded technology.

- (d) Study Data License. Subject to the terms and conditions of this Agreement, Ophthotech hereby grants to Novartis an exclusive, royalty-free, fully paid-up (except as otherwise set forth in Section 4.09(f)) right and license, with the right to grant sublicenses as set forth in Section 3.01(f), under Ophthotech's rights in (i) study data Controlled by Ophthotech from any Ophthotech-sponsored clinical trials of Fovista conducted prior to the Effective Date or pursuant to the Existing Fovista Clinical Program, or any study data Controlled by Ophthotech arising from the Investigator Sponsored Clinical Study of Fovista as to which Ophthotech had entered into as of the Effective Date, without the need for any election under Section 4.09(f) or payment of related Development Costs, and (ii) effective upon Novartis' election to opt in to any other Ophthotech-sponsored study under Section 4.09(f), the data from such other study, in each case ((i) and (ii)) to use such study data as necessary to Develop and Commercialize Products in the Field for the Novartis Territory (including the right to cross reference or include such study data in regulatory filings made with Regulatory Authorities for the Novartis Territory). In addition, Novartis shall have the right to use any information concerning any adverse events, and any product quality and product complaints involving adverse events, related to Products, sufficient to enable Novartis (or its applicable Affiliate or Sublicensee) to comply with its legal and regulatory obligations, without the requirement to opt in and share Development Costs, as specified in Section 4.09(f).
- (e) <u>Trademark License</u>. Subject to the terms and conditions of this Agreement, Ophthotech hereby grants to Novartis an exclusive right and license, with the right to grant sublicenses as set forth in Section 3.01(f), to use any Product Trademark Controlled by Ophthotech in connection

with Developing, Manufacturing and Commercializing Products in the Field for the Novartis Territory.

(f) Sublicenses; Other Third Party Arrangements.

(i) Novartis may, subject to Sections 3.01(g), (h), (i) and (j) and the provisions of this Section 3.01(f) below, sublicense the rights granted to it by Ophthotech under this Agreement at any time at its sole discretion. In any sublicense granted by Novartis, Novartis will include provisions that are sufficient to require the Sublicensee to satisfy all obligations under this Agreement that are applicable to Sublicensees and to enable Novartis to comply with its obligations under this Agreement. Except where a shorter notice period is required to comply with Sublicensee obligations under Existing Fovista Agreements, Novartis shall notify Ophthotech in writing of the identity of each Sublicensee within [\*\*] days following the grant of any sublicense hereunder, and shall notify Ophthotech in writing of the termination of any sublicense agreement within [\*\*] days following such termination. Novartis may exercise its

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rights and perform its rights and obligations under this Agreement itself or through any of its Affiliates. In addition, Novartis may subcontract to Third Parties the performance of Novartis' tasks and obligations with respect to the Development and Commercialization of the Product as Novartis deems appropriate.

- (ii) In the five (5) Major European Countries and Japan, from the Effective Date until the [\*\*] anniversary of First Commercial Sale of a Product in the applicable Major European Country or Japan, Novartis shall not, without Ophthotech's prior written consent, which Ophthotech may withhold in its discretion (A) grant any sublicenses to Third Parties; (B) contract with Third Parties for commercial arrangements, including promotion, co-marketing, or field force agreements, to outsource more than [\*\*] percent ([\*\*]%) of the applicable Commercialization activities in the applicable country; (C) contract with agents for regulatory activities; or (D) enter into Third Party distribution agreements under which the Third Party buys and sells Product for its own account.
- (iii) In the five (5) Major European Countries and Japan, after the [\*\*] anniversary of First Commercial Sale of a Product in the applicable Major European Country or Japan, Novartis shall not, without Ophthotech's prior written consent, which Ophthotech shall not unreasonably withhold, condition or delay, appoint a Third Party for any of the activities listed above in clauses (A), (B), (C) or (D) of subsection 3.01(f)(ii) for Commercialization of any Product, provided that Ophthotech may take into account the capabilities in the Field of the proposed Third Party in determining whether to give such consent. Novartis shall provide Ophthotech with written notice of its intent to appoint a Third Party for any of the activities listed above in clauses (A), (B), (C) or (D) of subsection 3.01(f)(ii) for Commercialization of any Product in any of the five (5) Major European Countries or Japan and Ophthotech shall, for a period of [\*\*] days after receipt of such notice, have an opportunity to provide Novartis with a proposal pursuant to which Novartis would grant such distribution or other Commercialization rights to Ophthotech rather than to a Third Party. If Novartis, after considering Ophthotech's proposal in good faith, determines to grant such distribution or other Commercialization rights to Ophthotech, the Parties shall agree on terms for such rights and enter into an agreement on such agreed terms.
- (g) Archemix Agreement Requirements. The rights and licenses granted by Ophthotech to Novartis with respect to any Ophthotech Patent Rights Controlled by Ophthotech pursuant to the Archemix Agreement and sublicensed to Novartis hereunder (the "Archemix Patent Rights"), including, as applicable, in Section 3.01(a), Section 3.01(b) and Section 3.01(c) and in ARTICLE VIII, are subject to the terms and conditions of the Archemix Agreement as applicable to the scope of Novartis' rights and obligations under the Archemix Agreement and this Agreement. In furtherance and not in limitation of the foregoing, Novartis acknowledges and agrees that:
- (i) the following provisions of the Archemix Agreement (and all defined terms referenced therein) are incorporated herein by reference (with appropriate modifications to account for the identities of the parties to this Agreement): Sections 2.1.2 (Negative Covenant), 2.1.4 (Reversion of License Rights), 2.1.5 (Archemix-Gilead License Agreement), 6.3.3 (Effect of Challenge) and 9.2.2 (Termination for Challenge);

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- (ii) each sublicense granted by Novartis with respect to the Archemix Patent Rights shall be subject to, and consistent with, the terms and conditions of the Archemix Agreement and shall include the provisions set forth in clause (i) above;
- (iii) each sublicense granted by Novartis with respect to the Archemix Patent Rights shall contain and include provisions substantially similar to, and consistent with, the language provided in Sections 2.1.1 (Grant of License), 3.1.2 (Diligence), 4.3.1 (Royalties), and Article 5 (Treatment of Confidential Information) of the Archemix Agreement;
  - (iv) Novartis shall retain records and permit Archemix to audit such records as required by Section 4.6 of the Archemix
- (v) upon termination of the Archemix Agreement, any sublicense granted to Novartis under this Agreement and any further sublicense granted by Novartis, in each case with respect to the Archemix Patent Rights, shall be considered a direct license from Archemix as provided in Section 9.3 of the Archemix Agreement; and

Agreement;

- (vi) Novartis shall provide Ophthotech with a copy of each sublicense granted by Novartis with respect to the Archemix Patent Rights within [\*\*] days after execution, a copy of which Ophthotech shall have the right to provide to Archemix.
- (h) Nektar Agreement Requirements. The rights and licenses granted by Ophthotech to Novartis with respect to any Ophthotech Patent Rights Controlled by Ophthotech pursuant to the Nektar Agreement and sublicensed to Novartis hereunder (the "Nektar Patent Rights"), including, as applicable, in Section 3.01(a), Section 3.01(b) and Section 3.01(c) and in ARTICLE VIII, are subject to the terms and conditions of the Nektar Agreement as applicable to the scope of Novartis' rights and obligations under the Nektar Agreement and this Agreement. In furtherance and not in limitation of the foregoing, Novartis acknowledges and agrees that:

- (i) Novartis does not have, and will not grant any sublicense under the Nektar Patent Rights to any Person that has, a significant or material business (as determined from the perspective of a reasonable competitor in such business) in either or both: (A) manufacturing or supplying poly (ethylene glycol) ("PEG") or PEG derivatives; and (B) attaching PEG or PEG derivatives to pharmaceutical or biotechnology products, including licensing intellectual property or technology pertaining to attachment of PEG or PEG derivatives to pharmaceutical or biotechnology products;
- (ii) Nektar may, at its option, terminate the sublicense granted to Novartis hereunder with respect to the Nektar Patent Rights upon termination or expiration of the Nektar Agreement;
- (iii) Novartis shall enter into the agreements set forth in Section 2.1(e) of the Nektar Agreement with respect to inventions and confidential information;
- (iv) Novartis shall not judicially challenge the validity or enforceability of any Nektar Patents; Novartis' sublicense rights to the Nektar Patents shall terminate as set forth in Section 3.5 of the Nektar Agreement if Novartis so challenges the Nektar Patents;

- (v) Novartis shall be subject to Section 3.6 and Article 9 of the Nektar Agreement to the same extent as Ophthotech;
- (vi) Nektar shall have the exclusive manufacturing rights set forth in Section 4.1 of the Nektar Agreement;
- (vii) Nektar shall have the intellectual property ownership and other rights set forth in Section 4.10 of the Nektar Agreement;
- (viii) Novartis shall keep and maintain records of sales made and deductions taken pursuant to this Agreement, and to grant access to such records by Nektar's independent accountant to the same extent required of Ophthotech under the Nektar Agreement;
- (ix) each sublicense granted by Novartis with respect to the Nektar Patent Rights shall be subject to, and consistent with, the terms and conditions of the Nektar Agreement and shall include the provisions set forth in this Section 3.01(h); and
- (x) Novartis shall provide Ophthotech with an unredacted copy of each sublicense granted by Novartis with respect to the Nektar Patent Rights within [\*\*] days after execution, a copy of which Ophthotech shall have the right to provide to Nektar.
- (i) OSI Agreement Requirements. The rights and licenses granted by Ophthotech to Novartis with respect to any Ophthotech IP Controlled by Ophthotech pursuant to the OSI Agreement and licensed to Novartis hereunder (the "OSI IP"), including, as applicable, in Section 3.01(a), Section 3.01(b) and Section 3.01(c) and in ARTICLE VIII, are subject to the applicable terms and conditions of the OSI Agreement, and Novartis agrees to comply with the terms and obligations to which Ophthotech is subject under the OSI Agreement to the extent consistent with the scope of Novartis's rights and obligations under the OSI Agreement and this Agreement. In furtherance and not in limitation of the foregoing, Novartis acknowledges and agrees that:
- (i) upon termination of the OSI Agreement by OSI as a result of a breach under Section 3.3(c) thereof, Ophthotech must automatically grant, assign and transfer to OSI the rights set forth in Section 11.4(a) of the OSI Agreement;
- (ii) OSI shall have the option to terminate or assign to OSI Ophthotech's interests in this Agreement if and as required pursuant to Section 11.4(a)(iii) of the OSI Agreement;
  - (iii) OSI shall have the right to audit Novartis' records of sales of Products as set forth in Section 6.3(h) of the OSI
- (iv) Novartis shall provide Ophthotech with an unredacted copy of each sublicense granted by Novartis with respect to the OSI IP within [\*\*] days after execution, a copy of which Ophthotech shall have the right to provide to OSI; and

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- (v) Any sublicense purported to be granted by Novartis and not complying with the terms of this Section 3.02(i) shall be deemed invalid and of no effect until such time as the discrepancies are remedied.
- (j) Novo Agreement Requirements. The rights and licenses granted by Ophthotech to Novartis hereunder are subject to the applicable terms and conditions of the Novo Agreement, and Novartis agrees to comply with the terms and obligations to which Ophthotech is subject under the Novo Agreement to the extent consistent with the scope of Novartis's rights and obligations under the Novo Agreement and this Agreement. In furtherance and not in limitation of the foregoing, Novartis acknowledges and agrees that:
- (i) Each sublicense granted by Novartis hereunder shall include record-keeping and audit provisions that comply with Sections 2.2 and 2.3 of the Novo Agreement;
- (ii) Novo shall have the rights with respect to enforcement of certain patents as set forth in Section 5.2(a) of the Novo Agreement; and
- (iii) Any sublicense purported to be granted by Novartis and not complying with the terms of this Section 3.02(j) shall be deemed invalid and of no effect until such time as the discrepancies are remedied.

Section 3.02 <u>Grants by Novartis.</u>

Agreement;

(a) <u>Study Data License</u>. [\*\*] and the other terms and conditions of this Agreement, Novartis hereby grants to Ophthotech, effective upon Ophthotech's election to opt in to a Novartis-sponsored study under Section 4.09(f), an exclusive, royalty-free, fully paid-up right and license, with the

right to grant sublicenses, to use the study data from such study as necessary to Develop and Commercialize products comprising Fovista in the Field for the Ophthotech Territory (including the right to cross reference or include such study data in filings made with Regulatory Authorities for the Ophthotech Territory). However, Ophthotech shall not grant any sublicenses under this Section 3.02(a) to any Third Party in the Novartis Territory during the Term without Novartis' prior written consent, not to be unreasonably withheld, conditioned or delayed. In addition, Ophthotech shall have the right to use any information concerning any adverse events, and any product quality and product complaints involving adverse events, related to Products, sufficient to enable Ophthotech (or its applicable Affiliate or sublicensee) to comply with its legal and regulatory obligations, without the requirement to opt in and share Development Costs, as specified in Section 4.09(f).

(b) Ophthotech Product License. [\*\*] and the other terms and conditions of this Agreement, Novartis hereby grants to Ophthotech an exclusive, royalty-free, fully paid-up right and license, with the right to grant sublicenses, under the Novartis Collaboration IP, to Develop, Manufacture and Commercialize products comprising Fovista in the Field for the Ophthotech Territory. The license set forth in this Section 3.02(b) excludes all rights to technology within the Novartis Collaboration IP and such license shall not require Novartis to conduct any technology transfer or provide access to any technology.

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#### Section 3.03 Ophthotech Rights to Pre-Filled Syringes.

- (a) [\*\*] and the other terms and conditions of this Agreement, Novartis, on behalf of itself and its Affiliates, hereby grants to Ophthotech an exclusive option, exercisable by Ophthotech at any time prior to the [\*\*] anniversary of [\*\*] upon written notice to Novartis, to the exclusive rights to conduct clinical studies for Regulatory Approval purposes and Commercialize Pre-Filled Syringes for the Ophthotech Territory, in each case using syringes supplied by Novartis, an Affiliate of Novartis, or one or more Third Parties pursuant to a supply agreement entered into pursuant to Section 6.04, whether in connection with a Standalone Product, Co-Formulated Product or Co-Packaged Product, as the case may be.
- (b) Upon Ophthotech's exercise of such option, Novartis hereby grants to Ophthotech an exclusive, royalty-free, fully paid-up right and license, with the right to grant sublicenses, under Intellectual Property rights and Product Trademarks Controlled by Novartis, to conduct clinical studies for Regulatory Approval purposes and Commercialize the Pre-Filled Syringe in the Field for the Ophthotech Territory, in each case using syringes supplied by Novartis, an Affiliate of Novartis, or one or more Third Parties pursuant to a supply agreement entered into pursuant to Section 6.04; provided, however, that Ophthotech acknowledges that, with respect to any Pre-Filled Syringe comprising ranibizumab, Novartis does not as of the Effective Date Control the rights to Develop, Manufacture or Commercialize ranibizumab for the Ophthotech Territory.

### Section 3.04 Ophthotech Rights to Co-Formulated Products.

- (a) Novartis, on behalf of itself and its Affiliates, [\*\*] grants Ophthotech an exclusive option, exercisable upon written notice to Novartis by Ophthotech at any time until the [\*\*] anniversary of the date of [\*\*] (the "Co-Formulated Product Option Term"), to Develop, Manufacture and Commercialize any Co-Formulated Product (other than as a Pre-Filled Syringe for a Co-Formulated Product, which rights are governed by Section 3.03) in the Field for the Ophthotech Territory.
- (b) Ophthotech acknowledges that, with regard to the Co-Formulated Product comprising ranibizumab, Novartis does not as of the Effective Date Control the rights to Develop, Manufacture or Commercialize ranibizumab for the Ophthotech Territory. Upon Ophthotech's exercise of such option with respect to Co-Formulated Products comprising ranibizumab in the Ophthotech Territory, Ophthotech shall become obligated to pay Novartis the portion of the Development Costs for such Co-Formulated Products specified in Section 3.04(d) and Novartis hereby grants to Ophthotech an exclusive (subject to Novartis' obligation to grant licenses to Genentech solely relating to Lucentis under the Lucentis License Agreement), royalty-free, fully paid-up right and license, with the right to grant sublicenses, under Intellectual Property rights and Product Trademarks Controlled by Novartis, to Develop, Manufacture and Commercialize Co-Formulated Products comprising ranibizumab in the Field for the Ophthotech Territory. If Ophthotech requests that Novartis Manufacture and supply such Co-Formulated Products for the Ophthotech Territory and Novartis is then: (i) Manufacturing the Co-Formulated Product for the Novartis Territory and in the case of both (i) and (ii) above assuming Novartis or Third Party has the ability or capacity to Manufacture the Co-Formulated Product or facilitate such Manufacture for the Ophthotech Territory, the Parties will negotiate and agree on financial and

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other terms for such Manufacture and supply, and shall enter into a supply agreement on such agreed terms.

- (c) Upon Ophthotech's exercise of such option with respect to Co-Formulated Products not comprising ranibizumab, Ophthotech shall become obligated to pay Novartis the portion of the Development Costs for such Co-Formulated Products specified in Section 3.04(d). The Parties will negotiate and agree on commercially reasonable financial and other terms with respect to Ophthotech's right to Develop, Manufacture and Commercialize Co-Formulated Products not comprising ranibizumab in the Field for the Ophthotech Territory, and shall enter into a license or collaboration agreement on such agreed terms promptly following Ophthotech's exercise of any option under this Section 3.04 with respect to Co-Formulated Products not comprising ranibizumab.
- (d) Following Ophthotech's exercise of any such option with respect to a Co-Formulated Product, Ophthotech shall share in the Development Costs for the Co-Formulated Product as shall be agreed by the Parties, which sharing shall, unless otherwise agreed by the Parties, include a reimbursement by Ophthotech to Novartis of [\*\*] percent ([\*\*]%) of such Development Costs incurred by Novartis prior to option exercise, and the bearing by Ophthotech of [\*\*] percent ([\*\*]%) of such Development Costs incurred from and after option exercise, and the Parties shall thereafter mutually agree on all Development Plan amendments and budgets for Development Plan activities with respect to such Co-Formulated Product. Ophthotech's payment of such Development Costs shall provide Ophthotech with rights to all study data for the Co-Formulated Product without the need to exercise the opt-in under Section 4.09(f) and any Development Costs paid by Ophthotech pursuant to Section 4.09(f) with respect to studies of the Co-Formulated Product shall be credited against the Development Costs payable by Ophthotech pursuant to this Section 3.04(d).
- (e) If Ophthotech exercises an option pursuant to this Section 3.04, Ophthotech shall, at Ophthotech's expense, be responsible for obtaining any rights not Controlled by Novartis (including with respect to ranibizumab) that are necessary or useful for Ophthotech to exercise its rights in the

Ophthotech Territory with respect to any Co-Formulated Product.

(f) Prior to [\*\*], the Parties' JOC representatives shall review in detail Novartis' Development efforts with respect to Co-Formulated Products regularly and at each alternating JOC meeting. If Novartis does not (x) reach commencement of preclinical development (i.e., animal studies) of a Co-Formulated Product on or before [\*\*], or (y) reach approval of FDP with respect to a Co-Formulated Product on or before [\*\*], assuming that Novartis is not required by a Regulatory Authority to conduct a Phase I Clinical Study or (z) continuously exercise Commercially Reasonable Efforts to Develop a Co-Formulated Product through Regulatory Approval thereof in the Novartis Territory, then the following provisions of this Section 3.04(f) shall apply:

(i) decisions over the Development of Co-Formulated Products for the Novartis Territory shall cease to be Novartis Casting Vote Matters; <u>provided</u>, <u>however</u>, that, subject to Section 2.08(c)(ii) and Section 4.05(a), Novartis shall have the sole right to select which Co-Formulated Product, as between a Co-Formulated Product comprising ranibizumab

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and a Co-Formulated Product comprising RTH258, is Developed and Commercialized for the Novartis Territory hereunder, and if multiple co-formulated products are successfully Developed, Novartis has the right at SDP to decide which of any such co-formulated products are Commercialized in the Novartis Territory;

- (ii) the Parties shall collaborate on the further Development of Co-Formulated Products for the Novartis Territory, and shall discuss and determine by mutual agreement whether to continue Development of the Co-Formulated Products as to which Novartis has commenced Development and whether to commence Development of additional or different Co-Formulated Products, which determinations shall be made based on relevant scientific, commercial and other considerations;
- (iii) if the Parties agree to Develop for Commercialization in the Novartis Territory a co-formulated product comprising Fovista and an anti-VEGF product Controlled by Ophthotech (an "Ophthotech Anti-VEGF Co-Formulated Product"), the Parties shall agree on the financial and other terms for and the respective roles and responsibilities of the Parties in such Development and Commercialization and, if the Parties reach agreement on such terms, enter into an amendment to this Agreement or a separate license or collaboration agreement setting forth such terms;
- (iv) the milestone payment set forth in Section 7.02(b)(iv) may be earned by Ophthotech through the Parties' Development of any Co-Formulated Product or Ophthotech Anti-VEGF Co-Formulated Product Developed pursuant to this Section 3.04(f) (it being understood that such milestone payment shall not become payable more than once regardless of how many Co-Formulated Products or Ophthotech Anti-VEGF Co-Formulated Products may be Developed); and
- (v) if applicable, the Parties shall negotiate and agree on appropriate changes to their financial obligations and rights with respect to the Co-Formulated Product in the Novartis Territory (including Novartis' responsibility for any additional Third Party license fees that may become payable based on necessary licensing of additional anti-VEGF product(s) for incorporation into Co-Formulated Product(s) as mutually agreed by the Parties pursuant to this Section 3.04(f)).
- Section 3.05 Ophthotech Anti-VEGF Products. Nothing in this Agreement shall limit Ophthotech or its Affiliates from Developing, Manufacturing or Commercializing worldwide any Ophthotech Anti-VEGF Product or acquiring or licensing from any Third Party any Ophthotech Anti-VEGF Product, either as a standalone product or, subject to Section 3.06 and the exclusive licenses granted to Novartis herein with respect to Products in the Novartis Territory, in combination with any other active pharmaceutical ingredient(s); provided that Novartis shall not be obligated to grant Ophthotech or any of its Affiliates Development, Manufacturing or Commercialization rights with respect to Novartis Anti-VEGF Products except as otherwise provided in this Agreement.

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#### Section 3.06 Ophthotech Rights as to Alternative Anti-PDGF Products.

- (a) <u>Development, Licensing or Acquisition</u>. Ophthotech and its Affiliates may Develop, license in or otherwise acquire Alternative Anti-PDGF Products during the Term (each, an "Ophthotech Alternative Anti-PDGF Product") in accordance with the terms and conditions of this Section 3.06.
- (b) <u>Ophthotech Territory</u>. Nothing in this Agreement shall limit Ophthotech or its Affiliates from Developing or Manufacturing worldwide, or Commercializing for the Ophthotech Territory, any Ophthotech Alternative Anti-PDGF Product.
- (c) Commercialization in Novartis Territory. Ophthotech or its Affiliates shall not Commercialize any Ophthotech Alternative Anti-PDGF Product in the Novartis Territory during the Term, except as may be permitted under this Section 3.06(c) below. If Ophthotech desires to Commercialize any Ophthotech Alternative Anti-PDGF Product in or for the Novartis Territory, then Ophthotech shall submit a proposal therefor to the JOC and, if Novartis determines to Commercialize such Ophthotech Alternative Anti-PDGF Product in the Novartis Territory, the Parties shall agree on the financial and other terms for and the respective roles and responsibilities of the Parties in such Commercialization and, if the Parties reach agreement on such terms, enter into a license or collaboration agreement setting forth such terms. Notwithstanding the foregoing, this Section 3.06(c) shall not restrict the acquiring Person or any of its Affiliates in any Ophthotech Change in Control from Commercializing anti-PDGF products, including any combination anti-PDGF product, in the Novartis Territory.

### Section 3.07 <u>Novartis Rights as to Alternative Anti-PDGF Products.</u>

(a) <u>Development and Manufacture Permitted</u>. Subject to the terms and conditions of this Agreement, including Section 3.07(d) below, Novartis and its Affiliates may Develop, license in or otherwise acquire an Alternative Anti-PDGF Product during the Term (a "Novartis Alternative Anti-PDGF Product"). Nothing in this Agreement shall limit Novartis or its Affiliates from Developing or Manufacturing any Novartis Alternative Anti-PDGF Product in the Field worldwide.

- (b) Restriction on Commercialization in the Ophthotech Territory. Novartis and its Affiliates shall not Commercialize any Novartis Alternative Anti-PDGF Product (whether as a standalone product or as a combination product) in or for the Ophthotech Territory during the Term except as otherwise permitted by and subject to Sections 3.07(d) and (e) below.
- (c) <u>Restriction on Commercialization in the Novartis Territory.</u> Novartis and its Affiliates shall not Commercialize any Novartis Alternative Anti-PDGF Product (whether as a standalone product or as a combination product) in the Novartis Territory before the expiry of [\*\*] years after the Effective Date. Thereafter Novartis and its Affiliates' Commercialization of any such Novartis Alternative Anti-PDGF Product in the Novartis Territory shall be subject to the provisions of Section 3.07(g) below.
- (d) <u>Restriction on In-licensing or Acquiring Alternative Anti-PDGF Products</u>. Novartis and its Affiliates shall not in-license or otherwise acquire (including by acquiring any Third Party with an anti-PDGF product) an Alternative Anti-PDGF Product from a Third Party within the period of [\*\*] years after the Effective Date. Novartis and its Affiliates shall not enter

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into any such in-license or acquisition on terms or conditions that would restrict in any manner whatsoever the exercise by Ophthotech of any of its rights pursuant to Section 3.07(e), Section 3.07(f) or Section 3.07(g) below.

- Commercialization of Novartis Alternative Anti-PDGF Products in the Ophthotech Territory. After completion of any Phase II (e) Clinical Study of such Novartis Alternative Anti-PDGF Product, Novartis shall notify Ophthotech of such completion and, if requested by Ophthotech, Novartis shall provide to Ophthotech a summary of the quality controlled first interpretable results of such study within [\*\*] Business Days after the date when the Novartis decision board confirms the accuracy thereof or, if requested by Ophthotech at a point in time later than when the Novartis decision board confirms the accuracy thereof, within [\*\*] Business Days after the date when Ophthotech requests such summary. [\*\*], Ophthotech shall have the option to Commercialize such Novartis Alternative Anti-PDGF Product in or for the Ophthotech Territory which option Ophthotech may exercise by notifying Novartis in writing during the periods specified in Sections 3.07(f)(ii) and Section 3.07(f)(iii). If Ophthotech determines to Commercialize such Novartis Alternative Anti-PDGF Product in the Ophthotech Territory, the Parties shall enter into a license or collaboration agreement setting forth the financial and other terms and conditions outlined in Section 3.07(f) below (which agreement shall include customary terms and conditions not outlined in Section 3.07(f), including the definition of net sales, calculation and duration of royalty obligations and reductions to royalties, that, where appropriate, shall generally parallel the analogous terms of this Agreement, insofar as this Agreement contains analogous terms), and thereafter the Intellectual Property relating to such Novartis Alternative Anti-PDGF Product that is Controlled by Novartis and that is reasonably necessary or useful for the Development, Manufacture or Commercialization of such Novartis Alternative Anti-PDGF Product in the Field shall be included in the Novartis IP. If Ophthotech does not exercise its option, Novartis and its Affiliates shall be free to Commercialize such Novartis Alternative Anti-PDGF Product in the Ophthotech Territory, but in no case earlier than following the [\*\*].
- (f) <u>Terms and Conditions for Commercialization of Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.</u> [\*\*], if Ophthotech exercises its option to Commercialize a Novartis Alternative Anti-PDGF Product in the Ophthotech Territory pursuant to Section 3.07(e):
  - (i) Novartis will have the option to co-promote the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.
- (ii) Ophthotech may elect to exercise its option within the [\*\*] time period following [\*\*], in which case the following financial terms will apply (subject to adjustment in accordance with Section 3.07(f)(iv)):
  - A. Ophthotech shall make the following payments to Novartis:
    - (I) A one-time option exercise fee of: \$[\*\*], which shall be in lieu of any Development Cost sharing with respect to Development Costs incurred by Novartis prior to Ophthotech's option exercise;

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- (II) Development Cost sharing: [\*\*]% of joint development costs going forward; and
- (III) A one-time U.S. Regulatory Approval milestone payment of: \$[\*\*] for U.S. Regulatory Approval of the Novartis Alternative Anti-PDGF Product.
- B. Ophthotech shall pay royalties to Novartis on net sales of the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory as follows:
  - (I) If Novartis does not exercise its option to co-promote the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory:
    - (x) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of standalone Novartis Alternative Anti-PDGF Product in the Ophthotech Territory; and
    - (y) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of combination of the anti-VEGF/Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.
  - (II) If Novartis exercises its option to co-promote the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory:
    - (x) Novartis shall be responsible for [\*\*]% of the sales force efforts for the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory, in accordance with a detailing plan

- established by Ophthotech, and Novartis shall pay all of Novartis' costs related to such copromotion;
- (y) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of standalone Novartis Alternative Anti-PDGF Product in the Ophthotech Territory; and
- (z) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of combination anti-VEGF/Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.

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- (iii) If Ophthotech does not elect to exercise its option pursuant to Section 3.07(f)(ii), Ophthotech may elect to exercise its option within the [\*\*] time period following Novartis' approval of SDP or, in the case of a Novartis Alternative Anti-PDGF Product in-licensed or acquired by Novartis at a point in Development that is later than the approval of SDP, within the [\*\*] time period following Novartis' written notice thereof to Ophthotech pursuant to Section 3.07(g), in which case the following financial terms will apply (subject to adjustment in accordance with Section 3.07(f)(iv)):
  - A. Ophthotech shall make the following one-time payments to Novartis:
    - (I) A one-time option exercise fee of: \$[\*\*], which shall be in lieu of any past Development Cost sharing with respect to the Novartis Alternative Anti-PDGF Product incurred by Novartis prior to Ophthotech's option exercise; and
    - (II) Development Cost sharing: Sharing of joint development costs going forward set out in the license and collaboration agreement entered into pursuant to Section 3.07(e); and
    - (III) A one-time U.S. Regulatory Approval milestone payment of: \$[\*\*] for U.S. Regulatory Approval of the Novartis Alternative Anti-PDGF Product.
  - B. Ophthotech shall pay royalties to Novartis on net sales of the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory as follows:
    - (I) If Novartis does not exercise its option to co-promote the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory:
      - (x) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of standalone Novartis Alternative Anti-PDGF Product in the Ophthotech Territory; and
      - (y) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of combination anti-VEGF/Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.
    - (II) If Novartis exercises its option to co-promote the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory:

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- (x) Novartis shall be responsible for [\*\*]% of the sales force efforts for the Novartis Alternative Anti-PDGF Product in the Ophthotech Territory, in accordance with a detailing plan established by Ophthotech, and Novartis shall pay all of Novartis' costs related to such copromotion;
- (y) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of standalone Novartis Alternative Anti-PDGF Product in the Ophthotech Territory; and
- (z) Ophthotech shall pay to Novartis a [\*\*]% royalty on net sales of combination anti-VEGF/Novartis Alternative Anti-PDGF Product in the Ophthotech Territory.
- (iv) If any adjustment is made to royalty rates payable on Net Sales of Products by Novartis in accordance with Section 7.04(f), proportional adjustments shall be made to the royalty rates payable by Ophthotech on net sales of Novartis Alternative Anti-PDGF Products and combination anti-VEGF/Novartis Alternative Anti-PDGF Products pursuant to this Section 3.07(f).
- (g) Novartis Alternative Anti-PDGF Products in the Novartis Territory. If Novartis or any of its Affiliates desires to Develop or Commercialize a Novartis Alternative Anti-PDGF Product in the Novartis Territory, Novartis shall give Ophthotech written notice thereof at the commencement of the first Phase II Clinical Study of such Novartis Alternative Anti-PDGF Product, or in the case of an Novartis Alternative Anti-PDGF Product in-licensed or acquired by Novartis that is already in Phase II Clinical Studies or at a later point in Development, not later than [\*\*] Business Days after such in-license or acquisition closes.

After completion of the Phase III Clinical Studies of such Novartis Alternative Anti-PDGF Product, Novartis will provide to Ophthotech Novartis' summary of the quality controlled first interpretable results of such data within [\*\*] Business Days after the date when the Novartis decision board confirms the accuracy thereof or, if later, within [\*\*] Business Days after the date when Ophthotech requests such summary. Novartis shall provide written notice to Ophthotech of Novartis' approval of SDP or, in the case of a Novartis Alternative Anti-PDGF Product in-licensed or acquired by Novartis at a point in Development that is later than the approval of SDP, within [\*\*] Business Days after the date of such in-license or acquisition, and, following such written notice, Ophthotech shall have a period of [\*\*] months to elect one of the three alternatives set forth in subsection (i), (ii) or (iii) below:

(i) To terminate this Agreement in accordance with Section 11.04.

(ii) To convert Novartis' licenses under Section 3.01 to Commercialize the Standalone Product in the Novartis Territory from exclusive to non-exclusive licenses.

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Following such conversion, Ophthotech would then be then free to Commercialize directly or with or through a Third Party the Standalone Product in the Novartis Territory. Additional terms to enable such Ophthotech Commercialization will be negotiated and agreed by the Parties at such time in good faith.

- (iii) To permit Novartis to continue with exclusive Commercialization of Products in the Novartis Territory concurrently with Novartis' Commercialization of the Novartis Alternative Anti-PDGF Product in the Novartis Territory, in which case Novartis shall continue to pay royalties to Ophthotech on Products as set out in Section 7.04 and on net sales of Novartis Alternative Anti-PDGF Products in the Novartis Territory (with the calculation of net sales and payment terms to parallel the terms of this Agreement applicable to the calculation of Net Sales and payment of royalties on Products) as follows:
  - (A) If Novartis or any of its Affiliates launches the Novartis Alternative Anti-PDGF Product prior to [\*\*], Novartis will pay royalties of [\*\*]% of net sales of standalone Novartis Alternative Anti-PDGF Product and [\*\*]% of net sales of combination anti-VEGF/Novartis Alternative Anti-PDGF Product in the Novartis Territory, which royalties shall be payable for a period of ten (10) years following the commercial launch thereof in the Novartis Territory. Such royalty obligations shall be limited to Novartis Alternative Anti-PDGF Products comprising the first alternative anti-PDGF compound that Novartis Commercializes, and not to Novartis Alternative Anti-PDGF Products comprising the subsequent anti-PDGF compounds that Novartis may Commercialize.
  - (B) If Novartis or any of its Affiliates commercially launches a Novartis Alternative Anti-PDGF Product later than [\*\*], no royalties shall be due on such Novartis Alternative Anti-PDGF Product. For the avoidance of doubt, royalties on Products payable to Ophthotech pursuant to Section 7.04 shall not be affected by this Section 3.07(g)(iii).
- (iv) Notwithstanding the foregoing provisions of this Section 3.07(g) and the provisions of Section 11.10(e), (A) the rights of Ophthotech pursuant to Sections 3.07(g)(ii) and 3.07(g)(iii) shall cease to apply and (B) the rights of Ophthotech to receive any milestone payment amounts pursuant to Section 11.10(e)(ii) shall cease to apply, as to both (A) and (B), following an Ophthotech Change in Control [\*\*]; provided that, if Ophthotech's rights to receive royalties pursuant to 3.07(g)(iii) cease pursuant to this Section 3.07(g)(iv) after an election by Ophthotech to receive such royalties, then upon such cessation of Ophthotech's previously elected right to receive such royalties, Ophthotech shall have the right, upon written notice to Novartis, to elect to terminate this Agreement pursuant to Section 3.07(g)(i) and this Agreement shall terminate accordingly. For the avoidance of doubt, other than as described in this Section 3.07(g)(iv), this Section 3.07(g)(iv) shall not otherwise affect the rights of Ophthotech to terminate this Agreement pursuant to Section 3.07(g)(i).

Section 3.08 <u>Rights Retained by Ophthotech</u>. Novartis shall receive only those rights of Ophthotech expressly granted by Ophthotech under the provisions of this Agreement, and any right of Ophthotech not expressly granted to Novartis under the provisions of this Agreement shall be retained by Ophthotech. For clarity, Ophthotech retains, without limitation, the rights

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(a) to exploit Ophthotech IP and Ophthotech Collaboration IP during the Term to Develop and Manufacture worldwide, and Commercialize for the Ophthotech Territory, Fovista and products comprising Fovista, and (b) to Develop, Manufacture and Commercialize Products in accordance with this Agreement and the Development Plan, Marketing Plan, and plans, budgets and updates thereto approved by the JOC, and otherwise to exercise Ophthotech's rights and perform Ophthotech's obligations under this Agreement, including to perform Ophthotech's supply obligations with respect to the API Supply.

Section 3.09 <u>Rights Retained by Novartis</u>. Ophthotech shall receive only those rights of Novartis expressly granted by Novartis under the provisions of this Agreement, and any right of Novartis not expressly granted to Ophthotech under the provisions of this Agreement shall be retained by Novartis.

Section 365(n) of the U.S. Bankruptcy Code. For purposes of Section 365(n) of the U.S. Bankruptcy Code (the "Code") and any similar laws in any other country in the Territory, all rights and licenses granted under or pursuant to any Section of this Agreement, including Section 3.01, Section 3.02, Section 3.03(b), Section 3.04(b), Section 11.10(b) and Section 11.10(c), are rights to "intellectual property" (as defined in Section 101(35A) of the Code). The Parties agree that the licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code and any similar laws in any other country in the Territory. Each Party hereby acknowledges that (a) copies of research data, (b) laboratory samples, (c) product samples, (d) formulas, (e) laboratory notes and notebooks, (f) data and results related to clinical trials, (g) regulatory filings and approvals, (h) rights of reference in respect of regulatory filings and approvals, (i) pre-clinical research data and results, and (j) marketing, advertising and promotional materials, in each case, that relate to such intellectual property, constitute "embodiments" of such intellectual property pursuant to Section 365(n) of the Code, and that the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless the licensor elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon written request therefor by the licensee following the rejection of this Agreement by or on behalf of the licensor. The provisions of this Section 3.10 are without prejudice to any rights the non-subject Party may have arising under the Code, Laws of other jurisdictions governing insolvency and bankruptcy, or other applicable Law. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the Code and any similar laws in any other country in the Territory: (A) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture or Commercialization of Products in the Territory; (B) the right to contract directly with any Third Party described in (A) to complete the contracted work, and (C) the right to cure any breach of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.

Third Party agreements with Novartis or its Affiliates relating to Lucentis, including agreements relating to a pre-filled syringe for Lucentis and the license and collaboration agreement between Novartis and Genentech Inc. ("Genentech") dated June 20, 2003 (as may be amended) (the "Lucentis License Agreement") are not subject to or affected by the terms of this Agreement, unless expressly specified. Novartis' obligations under this Agreement relating to Lucentis are subject to the terms of the Lucentis License Agreement and Novartis has disclosed to Ophthotech under the confidentiality agreement between the Parties material obligations pursuant to the Lucentis License Agreement to confirm Novartis' material rights and obligations under the Lucentis License Agreement which have the potential to impact aspects of this Agreement relating to Lucentis or where Novartis does not Control related Intellectual Property or grants licenses to Genentech relating to Lucentis (including the ownership of Lucentis trademarks and patents, Novartis' obligation to pay royalties to Genentech, certain notification provisions for Lucentis related regulatory approvals or clinical studies for Lucentis, Novartis' development and commercialization rights for Lucentis outside the United States, and Novartis' obligations to notify and permit Genentech to opt-in to profit and cost sharing for any deal such as this Agreement). At the Effective Date Novartis has not, pursuant to the confidentiality agreement between the Parties, discussed the fact of negotiations or pre-cleared the terms of this Agreement or amended the Lucentis License Agreement, but Ophthotech acknowledges that: (a) Novartis shall be required and entitled to disclose a redacted form of the terms of this Agreement as reasonably necessary relating to Lucentis to enable Novartis to comply with the terms of the Lucentis License Agreement, within [\*\*] calendar days after the Effective Date to Genentech under terms of confidentiality to meet Novartis' obligations under the Luce

# ARTICLE IV DEVELOPMENT AND REGULATORY ACTIVITIES

Section 4.01 General. Subject to Section 2.08(c), the Parties agree that their intention is for joint consensus decision-making relating to Development strategy for the Products within the Novartis Territory. Except as otherwise set forth in this ARTICLE IV, the JCD/RS shall coordinate the Development of the Products covered by the Development Plan to obtain Regulatory Approvals in the Novartis Territory, and, subject to the JOC's oversight, will direct the clinical Development and regulatory program for the Products in the Novartis Territory in accordance with the Development Plan. Except as otherwise set forth in this ARTICLE IV and except with respect to the Existing Fovista Clinical Program, the Development of the Products for the Novartis Territory shall be governed by, and each Party shall use Commercially Reasonable Efforts to conduct such Development in accordance with, the Development Plan. The Parties shall use Commercially Reasonable Efforts to seek a broad label for the Standalone Product ensuring market access and approval of the Standalone Product for use with Novartis Anti-VEGF Product(s) and with the approved Third Party anti-VEGF product(s) in the Field as specified in the Initial Development Plan. The Parties agree to conduct all their Development activities hereunder in accordance with all applicable Laws and, as applicable, Good Laboratory Practice, Good Manufacturing Practice and Good Clinical Practice. Ophthotech shall use

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Commercially Reasonable Efforts to conduct its activities under the Existing Fovista Clinical Program. Novartis shall use Commercially Reasonable Efforts to achieve the milestones set forth in Section 7.02(b). For clarity, compliance with the foregoing performance standard will not satisfy the more specific performance standards set out in Section 4.04, Section 4.05 and Section 4.06. THE PARTIES EXPRESSLY ACKNOWLEDGE AND AGREE THAT THERE IS NO GUARANTEE OF A SUCCESSFUL DEVELOPMENT AND THAT ANY DEVELOPMENT PROGRAM CONTAINS INHERENT RISKS. NEITHER PARTY SHALL BE LIABLE FOR FAILURES TO MEET SPECIFIED TIMEFRAMES FOR TECHNICAL IMPOSSIBILITY OR CAUSES OUTSIDE ITS REASONABLE CONTROL OR CAUSED BY THE OTHER PARTY.

Section 4.02 <u>Initial Development Plan</u>. An initial Development Plan that addresses the Development of the Products (except with regard to the Existing Fovista Clinical Program) for the Novartis Territory is attached hereto as <u>Exhibit C</u> (the "Initial Development Plan"). The JOC will work to ensure that there is coordination of patient enrollment efforts between the Phase III Clinical Studies in the Existing Fovista Clinical Program and the clinical studies for the Novartis Anti-VEGF Products.

# Section 4.03 <u>Development Plan Updates</u>.

- (a) Subject to the control and good faith consideration rights with respect to clinical studies as described in Section 4.08, updates to the Development Plan will be prepared by the Parties under the guidance of the JCD/RS, and the JOC will be responsible for approving such updates on at least an annual basis until the completion of the Development activities covered by the Development Plan.
- (b) With respect to any update to the Development Plan covering any Calendar Year for which the Parties will be sharing any Development Costs pursuant to Section 3.04(d) or Section 4.09(f), the JCD/RS shall submit such update with corresponding budget(s) for such jointly funded activities to the JOC for review and approval such that JOC preliminary approval would occur no later than July of the prior Calendar Year. Upon the JOC's preliminary approval, such update shall be submitted to each Party for its internal budgeting process with a target for final approval by the JOC by November of the prior Calendar Year, at which time any updates will be appended to the Development Plan.
- (c) The JCD/RS may also develop and submit to the JOC from time to time other proposed substantive amendments to the Development Plan. The JOC shall review such proposed amendments presented by the JCD/RS and may approve such proposed amendments or any other proposed amendments that the JOC may consider from time to time in its discretion and, upon such approval by the JOC, the Development Plan shall be amended accordingly. Such substantive amendments and updates to the Development Plan, including any joint activity budgets contained in the Development Plan, shall not be effective without the approval of the JOC.

- Section 4.04 <u>Development of the Standalone Product.</u>
- (a) Following the Effective Date, Ophthotech shall be solely responsible for conducting the Existing Fovista Clinical Program at Ophthotech's expense.
- (b) Novartis shall use Commercially Reasonable Efforts to perform at Novartis' expense (except as set forth in Section 4.09(f))

  Development activities for the Standalone Product for the Novartis Territory, including those set forth in the Initial Development Plan, which activities include Development activities beyond the Existing Fovista Clinical Program that the Parties as of the Effective Date anticipate will be necessary for Regulatory Approval of the Standalone Product in the Novartis Territory, and shall pursue Regulatory Approval of the Standalone Product in the Novartis Territory in accordance with the Initial Development Plan. In furtherance and not in limitation of the foregoing, Novartis shall use Commercially Reasonable Efforts to perform the following Development activities for the Standalone Product in accordance with the timeframes set forth below:
  - (i) [\*\*]; and
  - (ii) [\*\*].
- (c) The Parties hereby acknowledge and agree that it is the intent of the Parties that in the Novartis Territory (i) the Parties will seek Regulatory Approval for the Standalone Product prior to seeking Regulatory Approval for any other Product, including a Co-Packaged Product or a Co-Formulated Product unless otherwise agreed by the Parties and (ii) Novartis will seek pricing and reimbursement approval for and launch the Standalone Product prior to seeking pricing and reimbursement approval for and launching a Combination Product, unless agreed by the Parties.
- (d) Novartis shall determine the budget for Development activities for the Standalone Product for the Novartis Territory in its discretion, <u>provided that</u> such budget shall be consistent with Novartis' Development diligence obligations set out in Section 4.01 and Section 4.04(b). The Development Plan for the Standalone Product shall include the requisite clinical trials and regulatory activities to support Regulatory Approval and pricing and reimbursement approval within the Novartis Territory.

# Section 4.05 <u>Development of Co-Formulated Products</u>.

(a) Novartis shall use Commercially Reasonable Efforts to technically develop at Novartis' expense (except as set forth in Section 3.04(c)) both a Co-Formulated Product with Fovista and RTH258 and a Co-Formulated Product with Fovista and ranibizumab, with the decision as to which one or both of these two (2) Co-Formulated Product(s) is approved by Novartis for full Development and to Commercialize in the Novartis Territory both to be determined by Novartis in its sole discretion, and Ophthotech's option pursuant Section 3.04(a) shall apply only to those Co-Formulated Product(s) Novartis determines to Commercialize in the Novartis Territory. Following such determination, Novartis shall use Commercially Reasonable Efforts to Develop the Co-Formulated Product(s). In furtherance and not in limitation of the foregoing, Novartis shall use Commercially Reasonable Efforts to perform the following

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Development activities for Co-Formulated Products in accordance with the timeframes set forth below:

- (i) [\*\*]; and
- (ii) [\*\*]
- (b) Prior to Ophthotech's exercise of its option to Commercialize a Co-Formulated Product in the Ophthotech Territory as set forth in Section 3.04(a), Novartis shall determine the budget for such Development in its discretion, provided that such budget shall be consistent with Novartis' Development diligence obligations set out in Section 4.01 and Section 4.05(a), and provided further that Novartis shall, upon request from Ophthotech from time to time, provide Ophthotech with reasonable summary information regarding its incurred Development Costs and budget for such Development activities and such other technical and other information as reasonably requested by Ophthotech so that Ophthotech has reasonable visibility into the technical challenges and Development Costs it would be required to pay should it exercise its option to Commercialize such Co-Formulated Product in the Ophthotech Territory in accordance with Section 3.04(a). The Development Plan for Co-Formulated Products shall include the requisite clinical trials and regulatory activities to support Regulatory Approval and pricing and reimbursement approval within the Novartis Territory.

# Section 4.06 <u>Development of Pre-Filled Syringe</u>.

- (a) Novartis shall use Commercially Reasonable Efforts to Develop at Novartis' expense the Pre-Filled Syringe in the Field for the Standalone Product and a Co-Formulated Product for the Novartis Territory in accordance with the Development Plan. In furtherance and not in limitation of the foregoing, Novartis shall use Commercially Reasonable Efforts to [\*\*].
- (b) Ophthotech shall have the right to opt in for the conduct of clinical studies for Regulatory Approval purposes and Commercialization of the Pre-Filled Syringe for and in the Ophthotech Territory in accordance with Section 3.03, and, following any such opt in, the Parties shall discuss and agree on the related requirements and timeframes to be included in an update to the Development Plan and Novartis shall use Commercially Reasonable Efforts to ensure that Ophthotech shall receive from Third Parties any licenses needed to conduct clinical studies for Regulatory Approval purposes for the Pre-Filled Syringe for and in the Ophthotech Territory; provided, however, that Ophthotech acknowledges that, with respect to any Pre-Filled Syringe comprising Lucentis, Novartis does not as of the Effective Date Control the rights to Develop, Manufacture or Commercialize ranibizumab for the Ophthotech Territory. Novartis shall reasonably cooperate with Ophthotech requests to implement modifications to the Pre-Filled Syringe at Ophthotech's expense as set forth in Section 4.09(e).
- Section 4.07 <u>Development of Co-Packaged Products</u>. Any Development of Co-Packaged Products shall, subject to Novartis' compliance with its obligations under Section 4.04, be at Novartis' discretion; <u>provided</u>, <u>that</u>, if Novartis elects to Develop a Co-Packaged Product, it shall use Commercially Reasonable Efforts to Develop such Co-Packaged Product, and all such Development shall be conducted, consistent with the Development Plan. If Novartis determines

that it will Develop a Co-Packaged Product, the Development Plan will be amended to include any required clinical trials and regulatory activities to support Regulatory Approval and pricing and reimbursement approval within the Novartis Territory for such Co-Packaged Product.

#### Section 4.08 Development Studies.

- (a) Existing Fovista Clinical Program; Ophthotech Territory. Prior to the Effective Date, Ophthotech has independently initiated the Existing Fovista Clinical Program. Novartis acknowledges and agrees that Ophthotech will lead, control and be responsible for (i) the continued execution of the Existing Fovista Clinical Program and (ii) other studies of the Standalone Product, or of the Pre-Filled Syringe if Ophthotech opts in pursuant to Section 3.03, that Ophthotech determines are necessary or desirable for Regulatory Approval or Commercialization in the Ophthotech Territory, and Ophthotech may conduct such studies anywhere in the world (other than Phase IV Clinical Studies, which Ophthotech may only conduct in the Ophthotech Territory). Ophthotech shall consider in good faith Novartis' comments relating to the Existing Fovista Clinical Program and such other studies to the extent the Existing Fovista Clinical Program data and data from such other studies will be used by Novartis for the Development and Commercialization of Products for the Novartis Territory under this Agreement.
- (b) Novartis Territory. Novartis will lead, control and be responsible for all studies other than the Existing Fovista Clinical Program that are deemed by Novartis to be necessary or desirable for Regulatory Approval and Commercialization of the Standalone Product in the Novartis Territory, for the Co-Formulated Product(s) in the Novartis Territory, for any Co-Packaged Product in the Novartis Territory, and for the Pre-Filled Syringe in the Novartis Territory, and Novartis may conduct such studies anywhere in the world (other than Phase IV Clinical Studies, which Novartis may only conduct in the Novartis Territory). [\*\*], Ophthotech shall have the right to review and approve study designs or revisions for Development in any country worldwide of any Product (including the Pre-Filled Syringe) conducted by Novartis, and to withhold such approval based on bona fide scientific or safety concerns or concerns relating to consistency with Ophthotech's global Development strategy for Fovista. If Ophthotech does not approve or provide input within [\*\*] Business Days after receipt, Novartis shall consider such study design or revisions as being approved by Ophthotech and Novartis shall proceed accordingly. Following the [\*\*], Ophthotech shall have the right to review any clinical study designs or revisions for clinical studies conducted by Novartis for Regulatory Approval in the Novartis Territory within [\*\*] Business Days after receipt, Novartis shall consider such study design or revisions as being accepted by Ophthotech and Novartis shall proceed accordingly. Without limiting the foregoing, Novartis shall reasonably cooperate with any Ophthotech request, subject to the other provisions of this Section 4.08 and Section 4.09, to modify the Development Plan and clinical study designs to satisfy criteria necessary for Regulatory Approval in the Ophthotech Territory.
- (c) <u>Proposed Studies</u>. Each Party shall notify and confer with the other Party through the JCD/RS in advance of any additional clinical study of a Product that such Party proposes to conduct.

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(d) Study Data. All study data shall be owned by the Party sponsoring the study hereunder. If a Party so elects and pays Development Costs for such study pursuant to Section 4.09(f), then such study data shall be licensed by the sponsoring Party to the other Party and its Affiliates for the permitted regulatory, Development and Commercialization purposes under and on the terms set out in ARTICLE III. Use of scientific publications, presentations or abstracts relating to the study data that are in the public domain, and use of study data to the extent necessary to comply with pharmacovigilance obligations under applicable Law, shall not require any such opt-in or payment. It is agreed and understood by the Parties that Ophthotech shall share with Novartis all Development and Regulatory information and final (and not interim unless pre-specified in the statistical analysis plan) quality controlled data available per the pre-specified statistical analysis plan necessary for the Development and Regulatory Approval of Products by Regulatory Authorities in the Novartis Territory with regard to (i) the Existing Fovista Clinical Program, (ii) other studies conducted after the Effective Date to which Novartis opts in pursuant to Section 4.09(f) and (iii) any clinical studies relating to Fovista initiated by Ophthotech prior to the Effective Date with respect to which such data is necessary for Regulatory Approval in the Novartis Territory.

#### Section 4.09 Development Costs.

- (a) Ophthotech shall be responsible for one hundred percent (100%) of Development Costs for (i) the Existing Fovista Clinical Program and (ii) subject to Section 4.09(f), the studies identified in Section 4.08(a) outside of the Existing Fovista Clinical Program that Ophthotech determines are necessary or useful for Regulatory Approval or Commercialization in the Ophthotech Territory (it being understood that no such studies are underway as of the Effective Date).
- (b) Subject to Section 4.09(e) and Section 4.09(f), Novartis shall be responsible for one hundred percent (100%) of Development Costs for clinical studies of the Standalone Product, the Co-Formulated Product, or the Co-Packaged Product performed solely to support a regulatory filing, or as a condition of receiving Regulatory Approval, or deemed by Novartis to be desirable for Regulatory Approval or Commercialization, in the Novartis Territory.
- (c) Subject to Section 4.09(e) and Section 4.09(f), Novartis shall be responsible for one hundred percent (100%) of Development Costs for the Development of the Pre-Filled Syringe for the Novartis Territory.
- (d) Subject to Section 3.04(a), Section 4.09(e) and Section 4.09(f), Novartis will be responsible for one hundred percent (100%) of Development Costs for the Combination Products for the Novartis Territory.
- (e) If [\*\*] requests that [\*\*] modify a clinical or technical study to support a regulatory filing, or as a condition of receiving Regulatory Approval, for a Product (including for the Pre-Filled Syringe, whether for the Standalone Product or for any Combination Product) in the Ophthotech Territory, and [\*\*] agrees to such request in accordance with Section 4.08(b), [\*\*] shall be responsible for [\*\*] percent ([\*\*]%) of [\*\*] incurred by [\*\*] with respect to such clinical or technical study as a result of implementing [\*\*] request, and the Parties acknowledge

that, at [\*\*] request, as to Combination Products and the Pre-Filled Syringe, such costs may be incurred prior to [\*\*], in order to provide funding for incremental costs required to modify the Development Plan therefor to satisfy criteria required for Regulatory Approval in the Ophthotech Territory. Any such [\*\*] paid by [\*\*] pursuant to this Section 4.09(e) shall be excluded from the calculation of Development Costs to be reimbursed by [\*\*] pursuant to Section 3.04(a) or Section 4.09(f).

- (f) If a Party (the "Requesting Party") desires to use the other Party's ("Controlling Party") study data from any study described in paragraphs (a)(ii) or (d) above for the Requesting Party's own Development or Commercialization purposes (and, in the case of Ophthotech, Ophthotech does not already have such right pursuant to Section 3.03(b) or Section 3.04, then the Requesting Party shall provide the Controlling Party with written notice thereof. Thereafter, the Requesting Party shall be responsible for reimbursing the Controlling Party for one hundred percent (100%) of past Development Costs (if any) and fifty percent (50%) of subsequently incurred Development Costs, in each case in accordance with the Development Plan with respect to the applicable study. Following any such opt in, no amendment to the Development Plan budget for future Development Costs for the applicable study shall be effective without each Party's written approval, and the Requesting Party shall only be required to reimburse post-opt-in Development Costs that were incurred in accordance with such budget. Notwithstanding this Section 4.09(f), each Party shall have the right to use any information concerning any adverse experiences, and any product quality and product complaints involving adverse experiences, related to Products, sufficient to enable such Party (or its applicable Affiliate or sublicensee) to comply with its legal and regulatory obligations, without the requirement to opt in to study data and share Development Costs with respect thereto, and the Controlling Party shall make any such data available to the other Party for such purposes.
- (g) Each Party shall notify and confer with the other Party through the JCD/RS in advance of any planned clinical study pursuant to Section 4.08(c) and provide the expected budget therefor so that each Party may exercise its opt-in right under paragraph (f) above to obtain rights to the study data in exchange for fifty percent (50%) of all Development Costs with respect to the applicable study. The Controlling Party will retain control over the design and conduct of any such clinical study following any such opt in, subject to Section 4.08.
- Section 4.10 <u>Regulatory Activities</u>. The Parties agree that their intention is for joint consensus decision-making relating to regulatory strategy for the Products in the Field for the Novartis Territory, subject to the provisions of this Section 4.10.
- (a) <u>Responsibilities</u>. The JCD/RS shall be responsible for all regulatory matters in the Novartis Territory arising under the Development Plan and with respect to the Existing Fovista Clinical Program, <u>provided that</u>:
  - (i) Novartis shall be the holder of Regulatory Approvals for Products in the Field in the Novartis Territory; and
- (ii) Ophthotech shall have final decision-making authority in the event of any disagreement with respect to regulatory matters relating to the Existing Fovista Clinical Program and with regard to the filing of applications for, and seeking of, EU Regulatory

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Approval for the Standalone Product, including decisions concerning the initial labelling of the Standalone Product based on the Existing Fovista Clinical Program, subject to Section 2.08(c)(i)(A).

## (b) Participation Rights.

- (i) Subject to Section 4.10(b)(iii), each Party shall have the right to participate in regulatory matters in the Novartis Territory (with Novartis to be the lead regulatory Party and Ophthotech to be an observer). Novartis shall also have the right to participate as an observer in formal FDA regulatory meetings for Regulatory Approval of the Standalone Product in the Ophthotech Territory and Novartis shall nominate one Novartis representative to participate in such FDA regulatory meetings. Ophthotech shall provide Novartis with reasonable advance notice of all such meetings and provide copies of all material documents relating to such meetings. Ophthotech shall notify Novartis of all Regulatory Approvals for the Products by the FDA.
- (ii) Subject to Section 4.10(a)(ii), Section 4.10(b)(iii) and Section 4.10(b)(iv), Novartis will be the lead regulatory party with respect to all material meetings and other material contact with Regulatory Authorities in the Novartis Territory.
- (iii) With regard to the Existing Fovista Clinical Program as it relates to EU Regulatory Approval of the Standalone Product, Ophthotech and Novartis shall discuss related regulatory activities. To prepare the submission, Ophthotech shall use Commercially Reasonable Efforts to provide Novartis with copies of the Common Technical Document and any other documents necessary for the preparation and submission of the application for Regulatory Approval for the Standalone Product. Novartis will be responsible for promptly preparing the filing to be submitted to the relevant Regulatory Authorities and Novartis shall make such filings as directed by Ophthotech. Novartis will provide Ophthotech with drafts of any documents or correspondence that Novartis plans to submit in connection with EU Regulatory Approval of the Standalone Product sufficiently in advance of submission so that Ophthotech may review, comment and approve such documents and such other correspondence. Ophthotech and Novartis shall jointly participate in and co-lead all material meetings and other material contact with such Regulatory Authorities pertaining to the Existing Fovista Clinical Program as to EU Regulatory Approval of the Standalone Product. Unless the Parties otherwise agree, Ophthotech shall nominate one Ophthotech representative to participate in such material meetings and other material contact with such Regulatory Authorities pertaining to the Existing Fovista Clinical Program as to EU Regulatory Approval of the Standalone Product. Novartis shall provide Ophthotech with reasonable advance notice of all such meetings and other contact and copies of all related documents and other relevant information. Each Party shall promptly inform the other Party of any contact, and will endeavor to include the other Party in any teleconference or meeting, that such Party has with any Regulatory Authority in the Novartis Territory relating to EU Regulatory Approval of the Standalone Product.
- (iv) Upon grant of Regulatory Approval for the Standalone Product in the Novartis Territory, Novartis shall comply with all requirements imposed by applicable Laws as the marketing authorization holder for the Standalone Product and other Products. Novartis shall be fully responsible for maintaining the Regulatory Approval for the Standalone Product in

the Novartis Territory and Novartis, its Affiliates and Sublicensees shall not take any steps that might undermine such Regulatory Approval.

- (v) Except as required by a Regulatory Authority or applicable Laws or to Novartis Affiliates, Novartis shall in no circumstances transfer any Regulatory Approval granted for the Standalone Product in the Novartis Territory to any Third Party without the prior agreement of Ophthotech.
- (vi) Subject to Section 2.08(c)(i)(A), Novartis shall be responsible, at its sole cost, for the conduct of the post-Regulatory Approval measures required by the applicable Regulatory Authorities as a condition of Regulatory Approval in relation to the Standalone Product in the Novartis Territory. Without limiting Ophthotech's rights under Section 4.10(b)(iii) and Section 4.10(b)(vii), Novartis shall keep Ophthotech reasonably informed of, and use reasonable efforts to consult with Ophthotech with respect to, any discussions between Novartis and the Regulatory Authorities in the Novartis Territory relating to such post-Regulatory Approval measures.
- (vii) With regard to all regulatory activities for the Novartis Territory with respect to Products other than the Standalone Product in the EU, Novartis will be the lead regulatory party with respect to all material meetings and other material contact with Regulatory Authorities in the Novartis Territory for Products; provided, however, that, with regard to all regulatory activities for the Novartis Territory with respect to Products other than the Standalone Product in the EU, Ophthotech will have the right to participate as an observer in all material meetings and other material contact with the European Commission, the EMA and Regulatory Authorities in the Major European Countries and Japan pertaining to the Development of any Product or Regulatory Approval. Novartis shall provide Ophthotech with reasonable advance notice of all such meetings and other contact and advance copies of all related documents and other relevant information relating to such meetings or such other contact. Novartis and Ophthotech shall discuss any material documents or other material correspondence that Novartis is planning to submit in connection with Regulatory Approvals from the European Commission and in the Major European Countries and Japan, including the proposed labeling for any Product. Upon Ophthotech's reasonable request therefor, Novartis shall provide Ophthotech with drafts of such documents or correspondence sufficiently in advance of submission so that Ophthotech may review and comment on such documents and such other correspondence and have a reasonable opportunity to influence the substance of such submissions, which comments shall be considered in good faith by Novartis. Novartis shall promptly provide to Ophthotech copies of any material documents or other material correspondence pertaining to the Product in the Major European Countries and Japan and shall promptly provide to Ophthotech all proposed labeling, in each case received from Regulatory Authorities in the Major European Countries and Japan (including the EMA). Novartis shall provide Ophthotech with English translations that are readily available of the documents and correspondence described in this Section 4.10(b)(vii).
- (c) <u>Costs</u>. The cost to obtain and maintain all necessary regulatory filings and Regulatory Approvals for Products will be borne by Novartis in the Novartis Territory and by Ophthotech in the Ophthotech Territory, with the exception of the filing fees for obtaining EU Regulatory Approval of the Standalone Product pursuant to the Existing Fovista Clinical Program, which shall be borne by Ophthotech.

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Section 4.11 Adverse Event and Product Complaint Reporting Procedures; Pharmacovigilance. The Parties shall enter into a pharmacovigilance agreement for the Products applying to the Novartis Territory and the Ophthotech Territory within [\*\*] days after the Effective Date, but no later than when Novartis commences any clinical study of a Product. Such pharmacovigilance agreement shall contain the specific terms, conditions and obligations of the Parties with respect to the collection, reporting and monitoring of all adverse drug reactions, adverse events, medical inquires, and other relevant drug or related device safety matters with respect to Products during the Term. Each Party acknowledges that its obligations under the pharmacovigilance agreement shall include the obligations imposed on each Party by the applicable Law. Each Party will (a) provide the other Party with all Product complaints, non-serious and serious adverse event information, and safety data from clinical studies, including related communications with and from Regulatory Authorities, hospitals, physicians or patients, in its control necessary or desirable for the other Party to comply with all applicable Laws with respect to the Products and (b) report and provide access to such information to the other Party in such a manner and time so as to enable the other Party to comply with all applicable Laws. With respect to Products that are Commercialized, Novartis shall maintain the global adverse event database at its expense and shall generate adverse event reports for Ophthotech's use in the Ophthotech Territory and at Ophthotech's sole expense. Ophthotech shall have access to all data in such global adverse event database. Novartis shall be responsible for submitting adverse events reports to the applicable Regulatory Authorities in the Novartis Territory, and Ophthotech shall be responsible for submitting serious adverse events reports to the applicable Regulatory Authorities in the Ophthotech Territory. In addition, each Party shall promptl

# Section 4.12 Recalls, Market Withdrawals or Corrective Actions; Decisions to Terminate or Suspend a Study Based on Safety Concerns.

- (a) If any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Products in the Novartis Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [\*\*] hours, advise the other Party thereof by telephone or email. Novartis, in consultation with Ophthotech, shall decide whether to conduct a recall, field correction, or withdrawal of Product in the Novartis Territory, and Ophthotech will make available to Novartis, upon request, access to all of Ophthotech's pertinent records that Novartis may reasonably request in connection with such decision. Novartis shall decide the manner in which to conduct such action (except in the case of a Regulatory Authority mandated action when Novartis may act without such advance notice and shall notify Ophthotech as soon as reasonably possible). Novartis shall have the right and responsibility, at its expense, to control such recall, field correction, or withdrawal in a manner consistent with its internal SOPs in the Novartis Territory.
- (b) If either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the Novartis Territory, or if either Party becomes aware of information relating to any Product that indicates that a unit or batch of such Product may not conform to the specifications therefor, or that potential adulteration, misbranding, or other issues have arisen that relate to the safety or efficacy of Products, it shall promptly so notify the other Party. To the extent practicable, the Parties shall

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whether any recall, field correction, or withdrawal is necessary or appropriate. Each Party shall maintain complete and accurate records of any recall, field correction, or withdrawal in its respective territory for such periods as may be required by applicable Laws.

- (c) If any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Products in the Ophthotech Territory, or if either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the Ophthotech Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [\*\*] hours, advise the other Party thereof by telephone or facsimile. Ophthotech shall decide whether to conduct a recall in the Ophthotech Territory and the manner in which any such recall shall be conducted and shall notify Novartis as soon as possible of any such decision. Novartis will make available to Ophthotech, upon request, all of Novartis' pertinent records that Ophthotech may reasonably request to assist Ophthotech in effecting any recall. Ophthotech shall bear the expense of any such recall.
- (d) The Party sponsoring or controlling any clinical study of a Product may terminate or suspend such clinical study if (i) a Regulatory Authority or safety data review board for such clinical study has required such termination or suspension, or (ii) such Party believes in good faith that such termination or suspension is warranted because of safety or tolerability risks to the study subjects. In either case, such Party shall promptly notify the other Party of such termination or suspension, and shall use all reasonable efforts to notify and consult with the other Party prior to taking such action.

# ARTICLE V COMMERCIALIZATION

Section 5.01 <u>General</u>. Subject to Section 2.08(c), the Parties agree that their intention is for joint consensus decision-making, taking into account both Parties' economic interests, relating to Commercialization of the Products within the Novartis Territory. Novartis shall Commercialize the Products within the Novartis Territory in accordance with the Product Positioning and Branding Strategy approved by the JOC.

Section 5.02 <u>Diligence</u>.

(a) Novartis shall use Commercially Reasonable Efforts to Commercialize both the Standalone Product and Combination Product(s), including a Co-Formulated Product and including promotion of the Standalone Product in accordance with the approved label therefor with Novartis Anti-VEGF Product(s) and with all approved Third Party anti-VEGF product(s) in the Field in the Novartis Territory. Such efforts will be determined individually for

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each Product without consideration of the other Product(s). For the avoidance of doubt, compliance with the foregoing general performance standard shall not satisfy the more specific performance standards set forth in paragraph (b) below.

- (b) Novartis shall use Commercially Reasonable Efforts to: (i) pursue Commercialization of the Standalone Product and Combination Product(s), including a Co-Formulated Product, promptly following Regulatory Approval thereof and in accordance with the JOC-approved Marketing Plan; (ii) Commercialize the Standalone Product and Combination Product(s), including a Co-Formulated Product, in at least the Major European Countries and Japan; and (iii) comply with the additional minimum resourcing levels applicable for resourcing by Novartis in the [\*\*] prior to launch of the Products up until [\*\*] years after the First Commercial Sale of the Products, to be mutually agreed by the Parties in the [\*\*] following Novartis' confirmation of SDP (written notice of which Novartis shall promptly provide to Ophthotech) and, upon such agreement, such minimum resourcing levels as additional performance standards shall be automatically included as an amendment to Exhibit J attached hereto. If Novartis is not Commercializing a Product in a specific country in the Novartis Territory that Ophthotech considers to represent a significant market opportunity for such Product, Ophthotech may bring such concern to Novartis' attention and Novartis agrees to discuss such concern with Ophthotech and reasonably consider alternatives for Commercializing such Product in such country that Ophthotech may propose, including if commercially practicable the appointment of a distributor in such country.
- Section 5.03 Product Trademarks. As part of the Product Positioning and Branding Strategy, the Parties, through the JCS, shall develop and propose, and the JOC shall consider and approve, the Product Trademarks.
- Section 5.04 Marketing Plan. An annual marketing plan will be prepared by the JCS and approved by the JOC by [\*\*] of each year for the succeeding year, which shall include Commercialization budgets and an activity plan (the "Marketing Plan"). The first annual marketing plan for each Product (the "Initial Marketing Plan") shall include detail specific to each of the Standalone Product and one or more Combination Product(s), including a Co-Formulated Product, that is typical of pharmaceutical industry marketing plans, including strategy for pricing and reimbursement approval and discounting strategy and those elements set forth in Exhibit F hereto, and will be approved by the JOC no later than [\*\*]. The JOC shall agree on the scope, extent and detail to ensure effective Commercialization to be included in the Initial Marketing Plan and each subsequent annual Marketing Plan. Each Marketing Plan that covers any of the period from [\*\*] prior to the anticipated launch of a Product until [\*\*] after the First Commercial Sale of such Product shall include minimum resourcing levels for such period. All Commercialization activities shall be conducted consistent with the approved Marketing Plan.
- Section 5.05 <u>Advertising and Promotional Materials</u>. Novartis shall develop and approve relevant written sales, promotion and advertising materials relating to the Products ("Promotional Materials") consistent with its standard operating procedures, for use in the Novartis Territory, that shall be consistent with the Product Positioning and Branding Strategy approved by the JOC and compliant with applicable Laws and the provisions of the applicable

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Regulatory Approvals. Copies of all Promotional Materials used in the Novartis Territory will be archived by Novartis in accordance with applicable local Law.

Section 5.06 <u>Pricing and Reimbursement</u>. Novartis and its Affiliates shall take the lead in all pricing and reimbursement approval proceedings relating to the Products in the Novartis Territory in accordance with the JOC-reviewed general pricing and reimbursement approval strategy for the Novartis Territory. Novartis and its Affiliates shall be responsible for negotiating the pricing for the Products in the Novartis Territory, which Novartis shall negotiate consistent with the discounting strategy approved by the JOC.

Section 5.07 <u>Sales and Distribution</u>. Novartis or its Affiliates or Sublicensees shall be responsible for booking sales of Products in the Novartis Territory and shall warehouse and distribute such Products in the Novartis Territory. If Ophthotech receives any orders for Products from purchasers in the Novartis Territory, it shall refer such orders to Novartis. If Novartis receives any orders for Products from purchasers in the Ophthotech Territory, it shall refer such orders to Ophthotech.

- Section 5.08 Other Responsibilities. Novartis shall be solely responsible for the following functions in the Novartis Territory:
- (a) Handling all returns of Product. If Product sold in the Novartis Territory is returned to Ophthotech, it shall promptly be shipped to a facility designated by Novartis; and
  - (b) Handling all aspects of Product order processing, invoicing and collection, distribution, inventory and receivables.

Section 5.09 Quid. Attached hereto as Exhibit G is a list identifying products to which Novartis has Development or Commercialization rights in the Field that may be eligible for development or commercialization by Ophthotech on terms and conditions to be agreed in writing by the Parties, which list Novartis may revise from time to time at its discretion by written notice to Ophthotech that includes the revisions. Ophthotech may also from time to time propose products to which Novartis has Development or Commercialization rights in the Field that may be eligible for development or commercialization by Ophthotech, and the Parties will discuss in good faith whether to add such products to Exhibit G. Beginning as of the Effective Date until [\*\*], Ophthotech may commence a process to obtain rights to any such product by providing a written notice of interest to Novartis. If Novartis determines to grant rights to any such product to Ophthotech, the Parties shall agree on terms for and the respective roles of the Parties with respect to such product and enter into a license or collaboration agreement on such agreed terms. However, the Parties agree and understand that Novartis and its Affiliates may, at their own discretion, divest, prune, license, or enter into any other arrangement for the development or commercialization of such product(s) at any time and with any Third Party prior to entering into any such agreement with Ophthotech, and Novartis shall provide Ophthotech with notice through the JOC if it intends to take any such action.

# ARTICLE VI MANUFACTURE AND SUPPLY

Section 6.01 General. Except as otherwise provided in this ARTICLE VI,

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- (a) Ophthotech shall have responsibility for and control over all Manufacturing and supply activities for the Existing Fovista Clinical Program and the API Supply; and
- (b) Novartis shall have responsibility for and control over all Manufacturing and supply activities for Products (excluding the API Supply) in the Field for the Novartis Territory.
- Section 6.02 <u>Lucentis Supply for Clinical Studies</u>. Novartis shall provide the Lucentis product free of charge for use in the Novartis Territory in the Existing Fovista Clinical Program from and after the Effective Date and in future Phase II Clinical Studies and Phase III Clinical Studies (including phase IIIb clinical studies) involving Fovista and Lucentis that may be conducted in the Novartis Territory under this Agreement.
- API Supply. Novartis and its Affiliates will exclusively purchase from Ophthotech and Ophthotech will exclusively supply to Section 6.03 Novartis all of Novartis', its Affiliates' and Sublicensees' requirements for API Bulk Drug Substance for purposes of Developing and Commercializing Products (including for use in clinical studies and for Development or commercial Manufacturing purposes) for the Novartis Territory ("API Supply"). Novartis shall pay Ophthotech for the API Supply at (a) [\*\*]. Within [\*\*] months after the Effective Date, the Parties shall enter into a clinical supply agreement (the "Clinical Supply Agreement") pursuant to which Ophthotech or Ophthotech Affiliates will provide API Supply to Novartis for use in the Development of Products for the Novartis Territory. If Novartis requires clinical supply of the API Bulk Drug Substance to conduct clinical studies prior to execution of the Clinical Supply Agreement, the Parties shall mutually agree on the terms of such supply through the JMS. Within [\*\*] months after the Effective Date, the Parties shall enter into a commercial supply agreement (the "Commercial Supply Agreement" and, collectively with the Clinical Supply Agreement, the "Supply Agreement") pursuant to which Ophthotech or Ophthotech Affiliates will provide API Supply to Novartis for use in the Commercialization of Products for the Novartis Territory. Novartis and its Affiliates and Sublicensees shall use the API Bulk Drug Substance provided by Ophthotech solely for the Development of Products in accordance with the Development Plan and for the Commercialization of Products in accordance with this Agreement. The Supply Agreement to be agreed by the Parties shall include customary contract manufacturing and supply conditions, including equitable supply allocation, to be reasonably agreed upon, back-up and business continuity measures, audit or inspection rights necessary to comply with Manufacturing requirements, cooperation in resolution of Product complaints and to ensure compliance with other Manufacturing responsibilities, nonconforming product acceptance and replacement terms for the API Bulk Drug Substance, and any customary quality, technical and regulatory requirements. The Parties will also enter into an appropriate quality agreement for the API Supply.

Section 6.04 <u>Pre-Filled Syringe Supply.</u>

(a) If Ophthotech exercises its option to opt-in to conduct clinical studies for Regulatory Approval purposes and Commercialization of the Pre-Filled Syringe for the Ophthotech Territory pursuant to Section 3.03, then, if such Pre-Filled Syringe is successfully Developed for the Novartis Territory, Novartis shall supply Pre-Filled Syringes to Ophthotech at

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Novartis' Manufacturing Cost for Development purposes (including for the Existing Fovista Clinical Program), and the Parties will discuss in good faith whether Novartis will provide commercial supply of Pre-Filled Syringes to Ophthotech directly or if such supply will be provided by a Third Party. Ophthotech shall provide Novartis with reasonable advance notice if Ophthotech elects to Commercialize the Pre-Filled Syringe in the Ophthotech Territory, with such advance notice period to be discussed and agreed by the Parties, it being understood that such period shall be sufficient to enable Novartis to establish additional capacity, as necessary.

- (b) If the Parties agree that Novartis will provide commercial supply of Pre-Filled Syringes to Ophthotech directly, Novartis shall supply the Pre-Filled Syringes to Ophthotech at [\*\*] pursuant to a supply agreement to be entered into by the Parties that will include equitable supply allocation, to be reasonably agreed upon, back-up and business continuity measures, audit or inspection rights necessary to comply with Manufacturing requirements, cooperation in resolution of Pre-Filled Syringe complaints and to ensure compliance with other Manufacturing responsibilities, non-conforming product acceptance and replacement terms for the API Bulk Drug Substance, reimbursing Novartis for significant investments related to establishing additional capacity for the Ophthotech Territory and any quality, technical and regulatory requirements.
- (c) If Novartis at its sole discretion determines that a Third Party will provide commercial supply Pre-Filled Syringes to Ophthotech, Novartis will use Commercially Reasonable Efforts to facilitate a direct relationship between Ophthotech and the relevant Third Party for commercial supply of the Pre-Filled Syringe for the Products to Ophthotech for the Ophthotech Territory on commercial terms to be negotiated and agreed directly by Ophthotech with such Third Party; provided that [\*\*].

# ARTICLE VII FINANCIAL PROVISIONS

Section 7.01 <u>Upfront Payment</u>. Novartis shall pay Ophthotech a non-refundable, non-creditable, one-time payment of two hundred million dollars (\$200,000,000), which amount includes consideration for the right to use the study data from the Existing Fovista Clinical Program. Ophthotech's invoice for such amount is set forth in Exhibit H hereto, which invoice shall be payable within [\*\*] following the Effective Date.

### Section 7.02 <u>Development and Approval Milestones</u>

(a) <u>Existing Fovista Clinical Program Enrollment Milestones</u>. Ophthotech will promptly notify Novartis in writing of the achievement of the following milestone events, which such notice will be accompanied by an invoice for the corresponding milestone payment. Novartis shall make the non-refundable, non-creditable, one-time payments to Ophthotech set forth below in accordance with Section 7.06 following the first-time actual achievement of the corresponding milestone event set forth below:

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Milestone Event			Payment	
(i)	Enrollment of an aggregate of [**] patients comprising the sum of [**]	\$	[**]	
(ii)	Enrollment of an aggregate of [**] patients comprising the sum of [**]	\$	[**]	
(iii)	[**] with an aggregate enrollment of at least [**] patients.	\$	[**]	

(b) <u>Regulatory Approval Milestones</u>. Novartis shall promptly notify Ophthotech in writing of the achievement of each regulatory approval milestone event below and Ophthotech shall issue an invoice for the corresponding milestone payment. Novartis shall make the corresponding non-refundable, non-creditable, one-time payment to Ophthotech set forth below in accordance with Section 7.06:

Milestone Event		Payment	
[**]	\$	[**]	
[**]	\$	[**]	
[**]	\$	[**]	
[**]	\$	[**]	

Section 7.03 <u>Sales Milestones</u>. Novartis shall promptly notify Ophthotech in writing of the achievement of each sales-related milestone event below and Ophthotech shall issue an invoice for the corresponding milestone payment. Novartis shall make the corresponding non-refundable, non-creditable, one-time payment to Ophthotech set forth below in accordance with Section 7.06:

Milestone Event		Par	Payment	
(a)	first four (4) consecutive Calendar Quarter period in which total aggregate Net Sales of Products in the Novartis Territory			
excee	exceed \$[**]		[**]	
(b)	first four (4) consecutive Calendar Quarter period in which total aggregate Net Sales of Products in the Novartis Territory			
excee	d \$[**]	\$	[**]	
(c)	first four (4) consecutive Calendar Quarter period in which total aggregate Net Sales of Products in the Novartis Territory			
excee	d \$[**]	\$	[**]	
(d)	first four (4) consecutive Calendar Quarter period in which total aggregate Net Sales of Products in the Novartis Territory			
excee	ed \$[**]	\$	[**]	
(e)	first four (4) consecutive Calendar Quarter period in which total aggregate Net Sales of Products in the Novartis Territory			
excee	d \$[**]	\$	[**]	

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The foregoing sales milestone payments may be earned based on Net Sales in the same or overlapping four consecutive Calendar Quarter period(s) (*e.g.*, if the first two milestone events were achieved in the first four consecutive Calendar Quarter periods after product launch, both milestone payments shall become payable). If a milestone payment set forth above in this Section 7.03 is earned based on Net Sales over a period that is shorter in duration than four Calendar Quarters, such payment shall become payable after the end of the earliest Calendar Quarter in which Net Sales sufficient to satisfy the applicable milestone event conditions were made.

For clarity, total aggregate Net Sales of Products for purposes of this Section 7.03 shall be calculated on a rolling basis with respect to each four (4) consecutive Calendar Quarter period, *i.e.*, following the end of a Calendar Quarter, such Calendar Quarter shall replace the earliest of the four Calendar Quarters previously included in total aggregate Net Sales of Products, and the other three Calendar Quarters previously included in total aggregate Net Sales of Products shall continue to be included in total aggregate Net Sales of Products along with the Net Sales of Products in the Calendar Quarter just ended.

#### Section 7.04 <u>Royalties</u>.

- (a) <u>During Full Royalty Term</u>. Subject to Section 7.04(b) and Section 7.04(d), Novartis shall pay to Ophthotech royalties on a Product-by-Product and country-by-country basis during the applicable Full Royalty Term equal to:
- (i) with respect to Standalone Products, the greater of (A) [\*\*] percent ([\*\*]%) of aggregate Net Sales of Standalone Products in such country by Novartis, its Affiliates or Sublicensees and (B) the [\*\*] times the number of units of Standalone Product sold in such country by Novartis, its Affiliates or Sublicensees; and
- (ii) with respect to Combination Products, the greatest of (A) [\*\*] percent ([\*\*]%) of the Standalone Product Net Price multiplied by the number of units of Combination Products sold in such country by Novartis, its Affiliates or Sublicensees, (B) [\*\*] percent ([\*\*]%) of aggregate Net Sales of Combination Products in such country by Novartis, its Affiliates or Sublicensees, and (C) the [\*\*] times the number of units of Combination Product sold in such country by Novartis, its Affiliates and Sublicensees.
- (b) Reduction for Loss of Market Exclusivity During Full Royalty Term. Subject to further reduction pursuant to Section 7.04(d), Novartis shall pay to Ophthotech royalties on a Product-by-Product and country-by-country basis, during any Calendar Year in the applicable Full Royalty Term for which a Loss of Market Exclusivity exists with respect to such Product in such country, on aggregate Net Sales of such Product in such country by Novartis, its Affiliates or Sublicensees in an amount equal to [\*\*] percent ([\*\*]%) of the royalties set forth in Section 7.04(a). Once Loss of Market Exclusivity exists with respect to a Product in a country, it will be deemed to continue to exist thereafter with respect to such Product in such country unless Ophthotech requests in writing that Loss of Market Exclusivity with respect to a Product in a country be re-evaluated, in which case the existence of such Loss of Market Exclusivity, and any corresponding reduction pursuant to this Section 7.04(b), shall depend on whether the criteria set

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forth in the definition of Loss of Market Exclusivity are still met with respect to such Product in such country.

- (c) <u>During Reduced Royalty Term</u>. Subject to further reduction pursuant to Section 7.04(d), Novartis shall pay to Ophthotech royalties on a Product-by-Product and country-by-country basis during the applicable Reduced Royalty Term on aggregate Net Sales of such Product in such country by Novartis, its Affiliates or Sublicensees in an amount equal to [\*\*] percent ([\*\*]%) of the royalties set forth in Section 7.04(a).
- (d) Reduction for Third Party Patent Rights. If Novartis (or its Affiliates or Sublicensees) is required to make royalty payments under any license granted under any agreement entered into with any Third Party for Patent Rights to Develop, Manufacture or Commercialize a Product, and the Parties had mutually agreed that such license was necessary to permit Novartis' use or incorporation of Fovista in any Product or any formulation technology used to incorporate Fovista into any Co-Formulated Product and had mutually agreed to the terms of such license in advance (each, a "Third Party License"), then, on a Calendar Quarter, country-by-country and Product-by-Product basis, Novartis may offset a percentage of such royalty amounts against its royalty obligations to Ophthotech with respect to the applicable Product, where such percentage is equal to the [\*\*]; provided, however, that such offset shall not reduce the royalty payable to Ophthotech for such Product by more than [\*\*] percent ([\*\*]%) of the otherwise payable royalty amount for such Product in any Calendar Quarter by operation of this provision. Any amount that Novartis is entitled to deduct but that is reduced by the limitation in the preceding sentence will be carried forward and Novartis may deduct such amount from subsequent royalties (subject always to the limitation in the preceding sentence) until the full amount that Novartis was entitled to deduct is deducted.
- (e) <u>Payments under Existing Fovista Agreements</u>. Notwithstanding Section 7.04(d) above, Ophthotech shall be responsible for the reporting and payment of royalty obligations, if any, due to Third Parties for Fovista and for Ophthotech IP that is licensed by Ophthotech and sublicensed to Novartis under this Agreement in accordance with the terms of the Existing Fovista Agreements.
- (f) <u>Adjustments to Royalty Rates</u>. Novartis shall notify Ophthotech if Novartis reasonably determines that Novartis' profitability with respect to a Product has been materially reduced as a result of government-mandated price decreases in any country in the Novartis Territory. In any such event, the Parties shall engage in good faith discussions as to whether to make any mutually agreed equitable adjustment to the royalty rates set forth in this Section 7.04 with respect to Net Sales of such Product in such country.
- Section 7.05 <u>Royalty Reports.</u> Within [\*\*] days after the end of each Calendar Quarter during any Full Royalty Term or Reduced Royalty Term, Novartis shall submit to Ophthotech a report, on a Product-by-Product and country-by-country basis, providing the Net Sales (including units sold) of Product(s) during such Calendar Quarter and Standalone Product Net Prices for such Calendar Quarter and the calculation of the applicable royalties under Section 7.04. Ophthotech shall issue an invoice to Novartis for royalties following receipt of such report.

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Section 7.06 <u>Payments</u>. The paying Party shall pay all correct invoices issued under this Agreement within [\*\*] days from date of invoice from the receiving Party, including invoices issued by Ophthotech for milestones and royalties under this ARTICLE VII and Development Costs under Section 4.09(f).

Section 7.07 Records; Audits. Each Party shall keep, and shall cause its applicable Affiliates and Sublicensees to keep, complete, true and accurate records in accordance to its Accounting Standards of the items underlying Development Costs, Net Sales, Manufacturing Costs and Third Party Patent Rights royalties, other license fees and other payments relating to the reports and payments required by this Agreement. Each Party and its applicable Affiliates and Sublicensees shall keep such books and records for at least [\*\*] years following the Calendar Year to which they pertain. Each Party will have the right [\*\*], at its own expense, to have an independent, internationally-recognized, certified public accounting firm (the "Auditor"), selected by such Party and reasonably acceptable to the other Party, review any such records of the other Party, its Affiliates and Sublicensees in the location(s) where such records are customarily maintained upon reasonable notice and during regular business hours and under obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement within the prior [\*\*] month period. Before beginning its audit, the Auditor shall execute an undertaking reasonably acceptable to the audited Party by which the Auditor agrees to keep confidential all information reviewed during the audit. The Auditor shall have the right to disclose to the Parties only its conclusions regarding any payments owed under this Agreement. Such inspection right shall not be exercised more than [\*\*] and not more frequently than [\*\*] with respect to records covering any specific period of time. In addition, the auditing Party

shall only be entitled to audit the books and records of the audited Party from the [\*\*] Calendar Years prior to the Calendar Year in which the audit request is made. The auditing Party agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any applicable Law. The Auditor shall provide its audit report and basis for any determination to the audited Party at the time such report is provided to the auditing Party before it is considered final. If the review of such records reveals that the audited Party has failed to accurately report information pursuant to this Agreement, then the audited Party shall promptly pay to the auditing Party any resulting amounts due under this Agreement together with interest calculated in the manner provided in Section 7.11. If the audited Party has underpaid by an amount greater than [\*\*] percent ([\*\*]%) of the amounts actually due for a Calendar Quarter under this Agreement, the audited Party shall pay the reasonable costs of such review.

- Section 7.08 Tax Matters. Each Party will be solely responsible for taxes on the payments made to such Party under this Agreement and will otherwise be responsible for its own tax obligations. Notwithstanding the foregoing, Novartis shall make all payments to Ophthotech hereunder from the United States or Switzerland, will not withhold any tax from payments made from the United States, and, for payments made from Switzerland, will not withhold any tax for so long as the applicable withholding rate in the double taxation treaty between the United States and Switzerland is zero percent (0%).
- Section 7.09 <u>Currency Exchange</u>. All payments to be made by Novartis to Ophthotech shall be made in U.S. Dollars, to an Ophthotech bank account able to receive U.S. Dollars. Net

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Sales amounts used to calculate royalties and milestones shall be converted to U.S. Dollars in accordance with Novartis' then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into U.S. Dollars. Novartis shall give Ophthotech prompt written notice of any changes to Novartis' customary and usual procedures for currency conversion, which shall only apply after such notice has been delivered and provided that such changes continue to maintain a set methodology for currency conversion.

- Section 7.10 <u>Blocked Payments</u>. If, by reason of applicable Laws in any country, it becomes impossible or illegal for Novartis or its Affiliate or Sublicensee to transfer, or have transferred on its behalf, royalties or other payments to Ophthotech, Novartis shall promptly notify Ophthotech of the conditions preventing such transfer and such royalties or other payments shall be deposited in local currency in the relevant country to the credit of Ophthotech in a recognized banking institution designated by Ophthotech or, if none is designated by Ophthotech within a period of [\*\*] days, in a recognized banking institution selected by Novartis or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Ophthotech.
- Section 7.11 <u>Late Payments</u>. The paying Party shall pay interest to the receiving Party on the aggregate amount of any payment that is not paid on or before the date such payment is due under this Agreement at a rate per annum equal to the lesser of (a) [\*\*] or (b) [\*\*], calculated on the number of days such payment is paid after the date such payment is due, and compounded monthly.
- Section 7.12 <u>Resolution of Disputes.</u> If there is a dispute, claim or controversy relating to any financial obligation by one Party to the other Party pursuant to this Agreement, such Party shall provide such other Party with written notice setting forth in reasonable detail the nature and factual basis for such good-faith dispute and each Party agrees that it shall seek to resolve such dispute within [\*\*] Business Days after the date such written notice is received. If no such resolution is reached by the Parties, the dispute shall be resolved through the procedures set forth in ARTICLE XII.

# ARTICLE VIII INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

Section 8.01 Ownership of Intellectual Property.

- (a) <u>Existing IP</u>. Nothing in this Agreement shall affect Ophthotech's ownership of the Ophthotech IP existing as the Effective Date or Novartis' ownership of the Novartis IP existing as of the Effective Date, which in each case shall remain owned by the Party having such rights.
- (b) <u>IP Arising in Collaboration</u>. Each Party shall promptly notify the other Party of any new Intellectual Property created by such Party during the Term in the performance of this Agreement. Any such Intellectual Property shall be owned as follows:
- (i) any such Intellectual Property solely related to Fovista shall be owned by Ophthotech, included within the Ophthotech IP and included in the licenses granted to Novartis pursuant to Section 3.01;

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- (ii) any such Intellectual Property solely related to a Novartis Anti-VEGF Product, and any Intellectual Property or other rights to the Pre-Filled Syringe invented, created or developed solely by or on behalf of Novartis, shall be owned by Novartis, included within the Novartis IP and included, if and as applicable, in the licenses granted to Ophthotech pursuant to Section 3.02;
- (iii) any other such Intellectual Property that is solely invented, created or developed by or on behalf of one Party or its Affiliates (and not by or on behalf of the other Party or its Affiliates) shall be owned by the inventing, creating or developing Party ("Novartis Collaboration IP" or "Ophthotech Collaboration IP", as applicable); and
- (iv) any other such Intellectual Property that is created jointly by or on behalf of both of the Parties or their Affiliates shall be jointly owned by the Parties on the basis of each Party having an undivided interest in the whole ("Joint Collaboration IP"). Subject to the terms and conditions of this Agreement, each Party shall have the right to exploit Joint Collaboration IP as it may determine, without any duty to account to the other Party or obtain the other Party's consent for any such exploitation.
- (v) Questions of inventorship or authorship for purposes of determining whether new Intellectual Property created during the Term in the performance of this Agreement is Novartis Collaboration IP, Ophthotech Collaboration IP, or Joint Collaboration IP shall be resolved in accordance with United States patent or copyright Laws, as applicable.

(c) <u>Assignment of Ownership</u>. Each Party shall and hereby does assign to the other Party any right, title and interest it may have in any Intellectual Property that is to be owned by the other Party pursuant to this Section 8.01, and agrees to execute such documents and take such other actions reasonably requested by the other Party, to the extent necessary to give effect to the ownership allocation set forth in this Section 8.01.

### Section 8.02 <u>Handling of Patent Rights</u>.

- (a) <u>By Novartis.</u> Novartis shall have the sole right to Handle Patent Rights included in the Novartis IP or the Novartis Collaboration IP worldwide ("Novartis Patent Rights").
- (b) <u>By Ophthotech</u>. Ophthotech shall have the sole right to Handle Patent Rights included in the Ophthotech IP or the Ophthotech Collaboration IP worldwide ("Ophthotech Patent Rights").
- (c) <u>Joint Patent Rights</u>. The Parties will jointly control the Handling of Patent Rights included in the Joint Collaboration IP ("Joint Patent Rights"). Ophthotech shall have primary responsibility for Handling Joint Patent Rights in the Ophthotech Territory and Novartis shall have primary responsibility for Handling Joint Patent Rights in the Novartis Territory. If a Party elects not to Handle any Joint Patent Right for which it has primary responsibility (or, after commencement of such Handling, desires to cease Handling any Joint Patent Right), then such Party shall notify the other Party of such election and such other Party shall be entitled to Handle such Joint Patent Right in the applicable jurisdiction.

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- (d) <u>Costs and Expenses</u>. The Party Handling any Patent Right under this Section 8.02 shall bear one hundred percent (100%) of the costs thereof.
- (e) <u>Cooperation</u>. Each Party agrees to cooperate with the other with respect to Handling Patent Rights pursuant to this Section 8.02. With respect to Joint Patent Rights, or any other Patent Right Covering any Product in the Field in the Novartis Territory, the Party responsible for Handling such Patent Rights shall provide the other Party with advance copies (which may be in draft form) of all material filings as well as copies of all material correspondence from the relevant patent office, in each case relating to such Patent Rights, and shall consider in good faith all comments from such other Party relating to such filings and correspondence.

### Section 8.03 <u>Third Party Infringement.</u>

- (a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Ophthotech Patent Rights, Novartis Patent Rights or Joint Patent Rights, in each case that Cover any Product in the Field in the Novartis Territory or (ii) other unauthorized use or violation of any of the Ophthotech IP, Novartis IP or Collaboration IP, in each case relating to any Product in the Field in the Novartis Territory, of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such known or suspected infringement or unauthorized use or violation.
- (b) <u>Enforcement Rights</u>. Subject to the provisions of any Third Party license agreement under which Ophthotech's rights in Ophthotech IP or Ophthotech Collaboration IP, or either Party's rights in the Joint Collaboration IP, are granted:
- (i) Ophthotech shall have the first right, but not the obligation, to institute, prosecute and control any action or proceeding that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement, unauthorized use, or violation of) or otherwise enforce any of the Ophthotech IP, Ophthotech Collaboration IP or Joint Collaboration IP against Third Parties Developing, Manufacturing or Commercializing products that are competitive with Products in the Field in the Novartis Territory through counsel of its own choice. Prior to instituting any such action or proceeding, Ophthotech will give Novartis at least [\*\*] days' notice of its intention to institute any such action or proceeding. Ophthotech shall consider in good faith any comments from Novartis prior to instituting any such action or proceeding. Novartis may elect to contribute [\*\*] percent ([\*\*]%) of the costs and expenses of such action or proceeding by providing written notice to Ophthotech within [\*\*] days of the notice specified in Section 8.03(a). Should Novartis elect to contribute [\*\*] percent ([\*\*]%) of the costs and expenses of such action or proceeding, the Parties agree that there will be joint consensus decision-making relating to enforcement strategy for the Products in the Field for the Novartis Territory; in the case there may be an adverse effect on the Ophthotech IP, the Ophthotech Collaboration IP or Joint Collaboration IP in the Ophthotech Territory, Ophthotech shall have final decision-making authority relating to such action.
- (ii) If Ophthotech fails to initiate a suit or take other appropriate action pursuant to Section 8.03(b)(i) within [\*\*] days of the notice specified in Section 8.03(a) (or

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within [\*\*] days in the case of any action brought under a non-U.S. version of the Hatch-Waxman Act), then Novartis may, in its discretion, provide Ophthotech with written notice of Novartis' intent to initiate a suit or take other appropriate action. If Novartis provides such notice and Ophthotech fails to initiate a suit or take such other appropriate action within [\*\*] days after receipt of such notice from Novartis, then Novartis shall have the right (but not the obligation) to bring an action against Third Parties Developing, Manufacturing or Commercializing products that are competitive with Products in the Field in the Novartis Territory. If Novartis is not permitted (e.g., for local legal reasons) to bring such action and requests Ophthotech to bring such action on Novartis' behalf, then Ophthotech shall bring such action at Novartis' sole cost and expense.

- (iii) Neither Party shall settle or compromise any action or proceeding under this Section 8.03(b) without the consent of the other Party, which consent shall not be unreasonably withheld.
- (c) <u>Novartis Sole Right to Enforce</u>. Subject to the provisions of any Third Party license agreement under which Novartis' rights in Novartis IP or Novartis Collaboration IP are granted, and subject to Ophthotech's rights pursuant to Section 3.04, Novartis shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement, unauthorized use, or violation of) or otherwise enforce any of the Novartis IP or Novartis Collaboration IP worldwide.

- (d) Ophthotech Sole Right to Enforce. Subject to the provisions of any Third Party license agreement under which Ophthotech's rights in Ophthotech IP or either Party's rights in the Collaboration IP are granted, Ophthotech shall have the sole right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement, unauthorized use, or violation of) or otherwise enforce (i) the Joint Collaboration IP in the Ophthotech Territory against Third Parties Developing, Manufacturing or Commercializing products that are competitive with Products in the Field, and (ii) subject to Section 8.03(b), the Ophthotech IP and the Ophthotech Collaboration IP worldwide.
- (e) <u>Conduct of Certain Actions; Costs.</u> The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to Section 8.03(b), Section 8.03(c) or Section 8.03(d), but with regards to Section 8.03(b) Ophthotech will consider in good faith any comments on the choice of counsel received from Novartis. If required under applicable Law in order for the initiating Party to initiate or maintain such suit, the other Party shall join as a party to the suit. Such other Party shall offer reasonable assistance to the initiating Party in connection therewith at no charge to the initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Section 8.03(b), Section 8.03(c) and Section 8.03(d), including the fees and expenses of the counsel selected by it, unless Novartis elects to contribute [\*\*] percent ([\*\*]%) of the costs in accordance with Section 8.03(b). The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

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- (f) Recoveries. With respect to any suit or action referred to in Section 8.03(b), any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:
- (i) first, the Parties shall be reimbursed for all costs incurred in connection with such proceeding paid by the Parties and not otherwise recovered; and
  - (ii) second, any remainder shall be paid [\*\*] percent ([\*\*]%) to Novartis and [\*\*] percent ([\*\*]%) to Ophthotech.
- (g) Patent Invalidity Claim. If a Third Party at any time asserts a counterclaim to a patent infringement claim initiated by a Party that any Ophthotech Patent Right or Joint Patent Right that Covers the Product in the Field is invalid or otherwise unenforceable (an "Invalidity Claim"), control of the response to such claim in the Field in the Novartis Territory shall, as between the Parties, be determined in the same manner as enforcement rights with respect to such Patent Right are determined pursuant to Section 8.03(b), with the time periods set forth in Section 8.03(b) shortened where necessary to provide Ophthotech sufficient time to respond without a loss of rights, and the non-controlling Party shall cooperate with the controlling Party in the preparation and formulation of such response, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld. If the Invalidity Claim does not arise in connection with a suit or action referred to in Section 8.03(b)(i), Control of and the costs and expenses of responding to the Invalidity Claim shall be borne by the Party responsible for Handling the applicable Patent Right in accordance with Section 8.02.
- Section 8.04 <u>Claimed Infringement.</u> If a Party becomes aware of any claim that the Development, Manufacture or Commercialization of a Product infringes or otherwise violates the intellectual property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, the Parties shall cooperate and shall mutually agree upon an appropriate course of action and any settlement of such claim. Each Party shall have an equal right to participate in any settlement discussions that are held with such Third Parties. If there is a dispute between the Parties as to whether or not a Third Party Patent Right Covers the Product, the Parties agree to select an independent patent counsel to decide whether or not the subject Third Party Patent Right Covers the Product, they will accept such determination for purposes of Section 7.04(d), if applicable. If the decision is that the subject Third Party Patent Right does not Cover the Product or is invalid, either Party may still obtain a license, but shall be solely responsible for any payment obligation to the Third Party. Each Party shall provide to the other Party copies of any notices it receives from any Third Party regarding any patent nullity actions, any declaratory judgment actions and any alleged infringement or other violation of Third Party intellectual property rights relating to the Development, Manufacture or Commercialization of the Products. Such notices shall be provided promptly, but in no event after more than [\*\*] days following receipt thereof.

Section 8.05 <u>Patent Term Extensions</u>. The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extension (including those extensions

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available under the Supplementary Certificate of Protection of Member States of the EU and other similar measures in any other country) wherever applicable to Patent Rights in the Novartis Territory Controlled by either Party that Cover a Product in the Field. The Parties shall, if necessary and appropriate, use Commercially Reasonable Efforts to agree upon a joint strategy relating to patent term extensions, but, in the absence of mutual agreement with respect to any extension issue in the Novartis Territory, the patent or the claims of the patent shall be selected on the basis of the scope, enforceability and remaining term of the patent in the relevant country or region. All filings and costs for such extensions shall be made by the Party responsible for Handling the applicable Patent Right in accordance with Section 8.02.

- Section 8.06 <u>License Recordals</u>. The Parties shall cooperate, if necessary and appropriate, with each other in recording any license agreements wherever applicable to Patent Rights in the Novartis Territory that Cover a Product in the Field at Novartis' sole cost and expense.
- Section 8.07 <u>Patent Marking</u>. Each Party agrees to comply with the patent marking statutes in each country in which any Product is sold by such Party, its Affiliates or its sublicensees.

Section 8.08 Trademarks.

(a) Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.

- (b) Unless otherwise agreed in writing by the Parties at the time of determining the Product Positioning and Branding Strategy, and subject to any Third Party rights in the relevant Trademarks, Ophthotech shall own the Product Trademarks for the name and logo of the Standalone Product worldwide, and Novartis will own the Product Trademarks for the name and logo of the Combination Products, the Product Trademark for the name and logo of the Pre-Filled Syringe and the Trademark for the name and logo of Novartis Anti-VEGF Products worldwide. The Party owning a Trademark pursuant to this Section 8.08(b) shall be exclusively entitled to register and be the owner of the domain names corresponding to or containing such Trademark in any generic Top Level Domains (gTLDs), including the new and to be introduced gTLDs. The Party owning a Trademark shall also own all goodwill associated therewith throughout the world.
- (c) All Product Trademarks and other Trademarks referred to in Section 8.08(b) shall, other than as set forth in Section 8.08(b), be owned by Novartis in the Novartis Territory and by Ophthotech in the Ophthotech Territory.
- (d) Each Party shall and hereby does assign to the other Party any right, title and interest it may have in any Trademark that is to be owned by the other Party pursuant to Section 8.08(b) and Section 8.08(c), and agrees execute such documents and take such other actions reasonably requested by the other Party, to the extent necessary to give effect to the ownership allocation set forth in Section 8.08(b) and Section 8.08(c).
  - (e) Neither Party shall use any Product Trademark to identify any product other than a Product.

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- (f) The Parties agree that the quality of the Products and the Manufacture and Commercialization thereof shall be consistent with the highest standards of quality in the pharmaceuticals industry. In addition, each Party, its Affiliates and Sublicensees shall comply strictly with the other Party's trademark style and usage standards that such other Party communicates to such Party from time to time in connection with the use by such Party, its Affiliates and Sublicensees of Trademarks Controlled by such other Party. Each Party shall at its own expense, at the request of the other Party from time to time, submit to such other Party for approval a reasonable number of production samples of any Product Commercialized by such Party, its Affiliates and Sublicensees using a Product Trademark Controlled by such other Party and related packaging materials, other than those Products Manufactured by or on behalf of such other Party. If the Party Controlling the applicable Product Trademark reasonably objects to the usage of such Product Trademark in connection with any sample (other than samples produced by or on behalf of such Party), it shall give written notice of such objection to the other Party within [\*\*] days of receipt by such Party of such sample, specifying the way in which such usage of such Party's Product Trademark fails to meet the style, usage or quality standards for the Product set forth in the first two sentences of this Section 8.08(f), and such other Party shall immediately cease, and shall cause its Affiliates and Sublicensees to cease, sale and distribution of any unit of the Product that fails to meet the style, usage or quality standards in the same manner as the sample objected to by such Party. If such other Party or any of its Affiliates or Sublicensees wishes to continue to distribute and sell such Product, such Party must remedy the failure and submit further samples to such Party for approval.
- Except for the governance requirement to jointly agree the Product Positioning and Branding Strategy and subject to any Third Party rights in the relevant Trademarks, Novartis shall be solely responsible for implementing such strategy and Trademark matters, including Product Trademark matters, in the Novartis Territory at Novartis' cost, including decision-making, filing, litigation, customs registrations and enforcement, and Ophthotech shall be solely responsible for implementing such strategy and Trademark matters, including Product Trademark matters in the Ophthotech Territory at Ophthotech's cost, including decision-making, filing, litigation, customs registrations and enforcement. Novartis shall have the first right to enforce the Product Trademarks in the Novartis' cost and with the reasonable information to and assistance of Ophthotech, and Ophthotech shall have the first right to enforce the Product Trademarks in the Ophthotech Territory, at Ophthotech's cost and with the reasonable information to and assistance of Novartis.
- (h) If either Party becomes aware of any infringement of any Product Trademark by a Third Party, such Party shall promptly notify the other Party. The Parties shall cooperate and inform each other of relevant activities in their respective territory and consider in good faith the other Party's feedback if there is the potential for an impact to the other Party's territory.
- (i) Except as otherwise stated in this Agreement, Novartis shall not, and shall ensure that its Affiliates and Sublicensees do not, without Ophthotech's prior written approval, use or seek to register any Trademark or domain name consisting of, or containing "Fovista" or any other Product Trademark of Ophthotech.

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(j) Except as otherwise stated in this Agreement, Ophthotech shall not, and shall ensure that its Affiliates and Sublicensees do not, without Novartis' prior written approval, use or seek to register any Trademark or domain name consisting of, or containing "Lucentis" or any other Product Trademark of Novartis, or any Trademark of Novartis for Novartis Anti-VEGF Products.

# ARTICLE IX CONFIDENTIALITY AND PUBLICITY

- Section 9.01 <u>Confidential Information</u>. Subject to the other provisions of this ARTICLE IX, each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. As used herein, "Confidential Information" means confidential strategy, development plans, research information, technology, devices, products, clinical trial designs, clinical and pre-clinical data or other business information, objectives or technical information in any form or medium of a Party or its Affiliates disclosed by or on behalf of a Party in connection with this Agreement, whether prior to, on or following the Effective Date and whether disclosed orally, electronically, by observation or in writing. The terms of this Agreement shall be considered Confidential Information hereunder. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 9.01 shall not apply to any Confidential Information that:
- (a) was known by the receiving Party prior to disclosure by the disclosing Party hereunder (as evidenced by the receiving Party's written records or other competent evidence);
  - (b) is or becomes generally known or part of the public domain through no fault of the receiving Party;

- (c) is disclosed to the receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party; or
- (d) is independently developed by personnel of the receiving Party who did not have access to the other Party's Confidential Information (as evidenced by the receiving Party's written records or other competent evidence).

In addition, if either Party is required to disclose Confidential Information of the other Party by applicable Law or legal process, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange, including Nasdaq, such Party shall provide prior notice of such intended disclosure to such other Party if possible under the circumstances and shall disclose only such Confidential Information of such other Party as is required to be disclosed.

Section 9.02 <u>Employee, Consultant and Advisor Obligations</u>. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's

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employees, consultants, advisors, licensors and permitted subcontractors, licensees and distributors, and to the employees, consultants, advisors and permitted subcontractors, licensees and distributors of the receiving Party's Affiliates, who in such Party's reasonable judgment have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially equivalent to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 9.01.

Section 9.03 Permitted Disclosures. Either Party may disclose to bona fide potential investors, lenders and acquirors/acquirees, and to such Party's consultants and advisors, the existence and terms of this Agreement to the extent necessary in connection with a proposed equity or debt financing of such Party, or a proposed acquisition or business combination, or to bona fide potential Sublicensees, so long as such recipients are bound in writing to maintain the confidentiality of such information in accordance with the terms of this Agreement. In addition, Ophthotech may disclose the existence and terms of this Agreement to the counterparties to the Existing Fovista Agreements and Novartis may disclose the existence and terms of this Agreement to counterparties to agreements to which Novartis is a party as of the Effective Date, to the extent necessary for Ophthotech and Novartis respectively to comply with their obligations under such agreements; provided that each such counterparty to whom Ophthotech or Novartis discloses such information is subject to obligations of confidentiality and non-use with respect to such information substantially equivalent to the obligations of confidentiality and non-use of Ophthotech pursuant to Section 9.01.

Section 9.04 <u>Responsibility for Compliance</u>. Ophthotech or Novartis, as applicable, shall remain responsible for any failure by any Person to whom such Party discloses the other Party's Confidential Information pursuant to Section 9.02 or Section 9.03 to treat such information as required under Section 9.01 (as if such Person were a Party directly bound to the requirements of Section 9.01).

# Section 9.05 <u>Publicity</u>.

- (a) The Parties shall issue press releases as set forth on <u>Exhibit K</u> hereto following the Effective Date.
- (b) Neither Party shall, without the prior written consent of the other Party, not to be unreasonably withheld or delayed, issue any other press release or make any public announcement (whether verbally or in writing) to any Third Party that (i) references the other Party (other than pre-agreed language for ownership of trademarks); (ii) references joint activities under this Agreement; and (iii) relates to this Agreement or the other Party. A Party's consent shall not be required to the extent such press release or public announcement (A) is required by securities law disclosure requirements or otherwise required by applicable Laws, or legal process, in which event the Party issuing such press release or making such public announcement will, to the extent possible, provide the other Party with advance notice and a draft thereof and reasonably consider any timely comment with respect thereto provided by such other Party, (B) is of any subject matter included in any prior press release or public announcement, or (C) is limited to any of the matters set forth in Exhibit I hereto (with respect to which Ophthotech shall provide Novartis with a copy of such press release or public

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announcement prior to public disclosure, if possible, for informational purposes, which copy shall be Ophthotech's Confidential Information prior to its public disclosure).

(c) Subject to Section 9.05(b) where consent is not required, any Party proposing to make a press release or public announcement requiring the other Party's consent shall provide the proposed text to the other Party for its review prior to the date of disclosure. The reviewing Party shall provide its consent (which consent may be conditioned on such Party's agreement to implement the reviewing Party's reasonable revisions to the proposed text) no later than [\*\*] Business Days after the proposing Party's delivery of the proposed text.

# Section 9.06 <u>Publications</u>.

- (a) Prior to EU Regulatory Approval of the Standalone Product, nothing herein (except the applicable provisions of Section 9.06(d)) shall prevent Ophthotech (or a Third Party on its behalf) from publishing or presenting data or results relating to Fovista, including from the Existing Fovista Clinical Program or any other studies conducted by Ophthotech for Regulatory Approval (including label extension studies) for Fovista in the Ophthotech Territory.
- (b) Subject to the restrictions provided below in this Section 9.06, Ophthotech may, as of the Effective Date, and Novartis may, following EU Regulatory Approval of the Standalone Product, publish or present the results of Development carried out by such Party on a Product following review by the other Party for patentability and protection of such other Party's Confidential Information.

- (c) Each Party shall provide the other Party and the JOC (or its nominated Subcommittee or Working Group) with a copy of each proposed publication pursuant to subsection (b) above at least [\*\*] days in advance of submission for publications in peer-reviewed publications and a least [\*\*] Business Days in advance of submission for posters, abstracts and oral presentations or scientific publications. If a proposing Party does not receive feedback from the other Party or the JOC (or its nominated Subcommittee or Working Group) during the applicable review period, then it is deemed that there is a non-objection by the receiving Party to the content of such publication.
- (d) The Parties will cooperate to remove a Party's Confidential Information following such Party's request and reasonably cooperate on timing for late-breaking or otherwise urgent submission requirements. A reviewing Party, acting in good faith, may delay publication of a publication proposed pursuant to subsection (b) above for up to [\*\*] days to secure related Intellectual Property rights in the subject matter of the publication.
- (e) The publications process set forth in this Section 9.06 shall not apply to Investigator Sponsored Clinical Studies or follow-on publications with similar subject matter in relevant countries after the first multi-site publication is agreed.
- Section 9.07 No Liability for Public Disclosures by Other Party. Nothing in this Agreement shall be construed to impose upon either Party any liability or other obligation (either to the other Party or to any other Person) with respect to any press release, publication or other form of public disclosure or statement of the other Party.

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# ARTICLE X REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS; INDEMNIFICATION

Section 10.01 <u>Representations of Authority.</u> Ophthotech and Novartis each represents and warrants to the other Party that, as of the Effective Date, it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation and it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement that it has the right to grant to the other the licenses granted pursuant to this Agreement, and that it has taken all corporate action required by applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement.

Section 10.02 <u>Consents.</u> Ophthotech and Novartis each represents and warrants to the other Party that, except for any Regulatory Approval, pricing or reimbursement approval, manufacturing approval or similar approval necessary for the Development, Manufacture or Commercialization of the Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Effective Date.

Section 10.03 No Conflict. Ophthotech and Novartis each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and the licenses granted or to be granted by such Party pursuant to this Agreement (a) do not conflict with or violate any requirement of any Law existing as of the Effective Date applicable to such Party, (b) do not conflict with or result in a breach of any provision of its organizational documents, and (c) do not materially conflict with, violate, breach or constitute a default under any contractual obligation of such Party or any of its Affiliates existing as of the Effective Date. Each Party shall comply with all Laws applicable to the Development, Manufacture and Commercialization of the Products.

Section 10.04 <u>Enforceability</u>. Ophthotech and Novartis each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

Section 10.05 No Debarment. (a) Ophthotech represents, warrants and covenants to Novartis that as of the Effective Date, Ophthotech nor any of its Affiliates, nor, to its knowledge, any other Person involved in the Development of any Product prior to the Effective Date has been debarred or is subject to debarment pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or comparable Laws in the Novartis Territory, as applicable, and (b) Ophthotech and Novartis each represents, warrants and covenants to the other Party that neither such Party nor any of its Affiliates will knowingly use in any capacity, in connection with the Development of any Product, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section, or comparable Laws in the Novartis Territory, as applicable. Each Party agrees to inform the other Party in writing immediately if it or any Person who is

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performing services hereunder is debarred or is the subject of a conviction described in Section 306 or comparable Laws in the Novartis Territory, as applicable, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment or conviction of such Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Development of any Product.

Section 10.06 <u>Additional Representations and Warranties of Ophthotech</u>. Ophthotech represents, warrants and covenants to Novartis that, as of the Effective Date:

- (a) <u>Exhibit A</u> sets forth a complete and accurate list of all Ophthotech Product Patent Rights in the Novartis Territory in existence as of the Effective Date, indicating the owner, licensor or co-owner(s) thereof if any such Ophthotech Product Patent Rights is not solely owned by Ophthotech.
- (b) Other than as set forth on Exhibit A or as provided in the Existing Fovista Agreements, Ophthotech: (i) is the sole and exclusive owner or exclusive licensee in the Field of all right, title and interest in and to the Ophthotech Product Patent Rights free from any and all claims, charges, equitable interests, liens, mortgages, options, licenses, assignments, powers of sale, retentions of title, rights of pre-emption, rights of first refusal or security interests of any kind and (ii) is listed in the records of the appropriate governmental agencies as the sole and exclusive owner of record for each registration, grant and application included in the Ophthotech Product Patent Rights.
- (c) Ophthotech has the right to use and disclose and to enable Novartis to use and disclose (in each case under appropriate conditions of confidentiality) all Know-How and Confidential Information included in the Ophthotech IP in the Field in the Novartis Territory, free, except as provided

in the Existing Fovista Agreements, from any and all claims, charges, equitable interests, liens, mortgages, pledges, options, licenses, assignments, powers of sale, retentions of title, rights of pre-emption, rights of first refusal or security interests of any kind.

(d) As to the Manufacture of Products by Novartis for the Novartis Territory or to supply Ophthotech, Novartis shall not be subject to the U.S. manufacturing preference provisions of Public Law 96 517 (35 U.S.C. 200-204), as amended, or any similar obligations under the Laws of any other country as a consequence of any government funding relationship to which Ophthotech or any of its licensors under the Existing Fovista Agreements is a party.

(e) Other than as set forth on Exhibit A, Ophthotech has obtained from all individuals who participated in any respect in the invention or authorship of any Ophthotech IP effective assignments of all ownership rights of such individuals in such Ophthotech IP, either pursuant to written agreement or by operation of law, and all of its employees, officers, and consultants have executed agreements or have existing obligations under applicable Laws requiring assignment to Ophthotech of all inventions made during the course of and as the result of their association with Ophthotech and obligating the individual to maintain as confidential Ophthotech's Confidential Information as well as confidential information of other Persons (including Novartis and its Affiliates) which such individual may receive, to the extent required to support Ophthotech's obligations under this Agreement.

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- (f) The Ophthotech Product Patent Rights are existing and, to Ophthotech's knowledge, are each valid and enforceable without any claims, challenges, oppositions, interference or other proceedings pending or threatened, Ophthotech has filed and prosecuted patent applications within the Ophthotech Product Patent Rights in good faith and complied with all duties of disclosure with respect thereto, and Ophthotech has not intentionally committed any act, or intentionally omitted to commit any act, that may cause the Ophthotech Product Patent Rights to expire prematurely or be declared invalid or unenforceable.
- (g) All material application, registration, maintenance and renewal fees in respect of the Ophthotech Product Patent Rights owned by Ophthotech have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining such Ophthotech Product Patent Rights.
- (h) Ophthotech is not aware of any claim made against it (i) asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of the Ophthotech Product Patent Rights or (ii) challenging Ophthotech's Control of the Ophthotech Product Patent Rights or making any adverse claim of ownership thereof. Ophthotech has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating any Ophthotech IP, nor have any such proceedings been threatened by Ophthotech, nor does Ophthotech know of any valid basis for any such proceedings.
- (i) Ophthotech has not granted any license to any Third Party under the Ophthotech IP that is materially inconsistent with the licenses granted to Novartis hereunder.
- (j) To Ophthotech's knowledge as of the Effective Date, the making, using, selling, offering for sale or importation of Fovista as a Standalone Product, as formulated and Manufactured as of the Effective Date, in the Novartis Territory as contemplated in this Agreement does not and will not infringe, interfere with or result in the misappropriation of any Third Party IP rights existing as of the Effective Date.
- (k) (i) No claim of infringement of the Patent Rights or Trademark rights of any Third Party or of misappropriation of any other Third Party IP has been made nor, to Ophthotech's knowledge, threatened against Ophthotech or any of its Affiliates with respect to the Development, Manufacture or Commercialization of Fovista, except as disclosed to Novartis by Ophthotech as of the Effective Date, and (ii) there are no other claims, judgments or settlements against or owed by Ophthotech or to which Ophthotech is a party or, to Ophthotech's knowledge, pending or threatened claims or litigation, in either case relating to Fovista.
- (l) All material information Ophthotech has made available to Novartis relating to Fovista and the Development of Fovista as conducted to date is accurate in all material respects and does not contain any untrue statement of a material fact.
- (m) Ophthotech will conduct all of its activities under this Agreement in a professional and workmanlike manner, consistent with prevailing industry practices.
- (n) Ophthotech has provided Novartis with complete and correct copies of each of the Existing Fovista Agreements as of the Effective Date. To Ophthotech's knowledge,

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such agreements remain in full force and effect as of the Effective Date and such agreements are the only agreements as of the Effective Date between Ophthotech and any Third Party pursuant to which Ophthotech is granting a sublicense to Novartis under this Agreement. Ophthotech represents and warrants to Novartis that, to Ophthotech's knowledge as of the Effective Date, Ophthotech is in compliance in all material respects with the terms of the Existing Fovista Agreements, and shall use Commercially Reasonable Efforts not to take or omit to take any action that would constitute a breach of any Existing Fovista Agreement and will not enter into any amendment to or terminate any Existing Fovista Agreement, which breach or amendment would be reasonably likely to have a material adverse effect on the Development, Manufacture or Commercialization of the Products in the Field in the Novartis Territory. Ophthotech shall provide Novartis promptly with notice of the occurrence of any such breach or amendment or termination (or Ophthotech's receipt of notice of an allegation of any such breach).

Section 10.07 <u>Additional Representations and Warranties of Novartis</u>. Novartis represents, warrants and covenants to Ophthotech that, as of the Effective Date:

(a) Without limiting Section 3.11, Novartis has not granted any license to any Third Party that is materially inconsistent with the licenses granted or to be granted to Ophthotech hereunder.

- (b) To Novartis' knowledge as of the Effective Date, the making, using, selling, offering for sale or importation of any Novartis Anti-VEGF Product, each as contemplated by this Agreement, does not and will not infringe, interfere with or result in the misappropriation of any Third Party IP existing as of the Effective Date.

  (c) All of its employees, officers, and consultants have executed agreements or have existing obligations under applicable Laws requiring assignment to Novartis of all inventions made during the course of and as the result of their association with Novartis and obligating the individual to maintain as confidential Novartis' Confidential Information as well as confidential information of other Persons (including Ophthotech and its Affiliates) which such individual may receive, to the extent required to support Novartis' obligations under this Agreement.

  (d) All material information Novartis has made available to Ophthotech relating to the Development, Manufacture or Commercialization of the Products in the Field, including the Novartis Anti-VEGF Products and the Pre-Filled Syringe, is accurate in all material respects and does not contain any untrue statement of a material fact.

  (e) To Novartis' knowledge after due inquiry of its Affiliates involved in pre-clinical or later stage Development or Commercialization of branded prescription pharmaceutical products in the Field, neither Novartis nor any of such Affiliates (i) have in-licensed any rights to any Alternative Anti-PDGF Product that is at a pre-clinical or clinical Development or Commercialization activities with respect to any Alternative Anti-PDGF Product, other than as set forth on Exhibit L hereto.
- (f) Novartis will conduct all of its activities under this Agreement in a professional and workmanlike manner, consistent with prevailing industry practices.
- (g) Novartis or one of its Affiliates solely owns the Patent Right referenced on Exhibit E and Novartis shall, within [\*\*] days after the Effective Date, provide Ophthotech with a complete and accurate list of all United States and Patent Cooperation Treaty (PCT) Novartis Patent Rights pending or issued as of the Effective Date that Cover RTH258, indicating the owner, licensor or co-owner(s) thereof if any such Novartis Patent Rights is not solely owned by Novartis.

# Section 10.08 Standstill.

- (a) In partial consideration of the rights and licenses granted to Novartis hereunder, Novartis hereby agrees that during the Restricted Period (as defined below), unless such shall have been specifically invited in writing by Ophthotech, none of Novartis, any controlled Affiliate of Novartis or any other Affiliate of Novartis who has received from Novartis confidential information concerning Ophthotech (and specifically excluding any Third Party advisers or representatives such as banks or law firms except to the extent acting on behalf of Novartis or any such Affiliate) will directly or indirectly:
  - (i) effect or seek, offer or propose to effect, or cause or participate in:
- A. any acquisition of any securities (or beneficial ownership thereof) of Ophthotech, or any rights to acquire any such securities (including derivate securities representing the right to vote or economic benefit of any such securities);
- B. any "solicitation" of "proxies" (as such terms are used in the proxy rules of the Securities and Exchange Commission) or consents to vote any voting securities of Ophthotech; or
- C. any acquisition of assets from Ophthotech that includes U.S. rights to Fovista (other than rights relating to the Co-Formulated Product);
- (ii) form, join or participate in a "group" (as defined in Section 13(d)(3) of the U.S. Securities and Exchange Act of 1934, as amended) (a "13D Group") with respect to any securities of Ophthotech; or
- (iii) take any action that might require Ophthotech to make a public announcement regarding any of the matters set forth in (i) above.
- (b) "Restricted Period" means the period commencing on the Effective Date and ending on the earlier of Regulatory Approval in the United States of the Standalone Product or EU Regulatory Approval of the Standalone Product.
- (c) Notwithstanding anything to the contrary contained in this Agreement, the restrictions set forth in this Section 10.08 shall not apply to any acquisition of assets or securities of Ophthotech, as debtor, by Novartis or its Affiliates in a transaction subject to the approval of

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the United States Bankruptcy Court pursuant to proceedings under the United States Bankruptcy Code.

- (d) Notwithstanding anything to the contrary contained in this Agreement, the restrictions set forth in this Section 10.08 shall not apply to (i) acquisition or ownership of up to three percent (3%) of any securities of Ophthotech made by or on behalf of Novartis or its Affiliates in the ordinary course of business for investment purposes in Third Party mutual funds or similar passive investment vehicles or any pension or employee benefit plan or trust; (ii) securities of Ophthotech held by a Person acquired by Novartis on the date such Person first entered into an agreement to be acquired by Novartis; or (iii) the acquisition or ownership of up to three percent (3%) of the outstanding shares in Ophthotech by Novartis or its Affiliates.
  - (e) The restrictions set forth in this Section 10.08 shall terminate immediately with no further force or effect:
- (i) for the period commencing when a Person or 13D Group not including Novartis or its Affiliates commences or announces its intention to commence a tender, exchange or other offer for voting securities representing more than fifty percent (50%) of the then-outstanding voting

securities of Ophthotech and ending upon the withdrawal or termination of such offer; if Ophthotech enters into an agreement with any Person other than Novartis or its Affiliates providing for any merger, sale, reorganization, recapitalization or other business combination or similar transaction (A) pursuant to which more than fifty percent (50%) of the outstanding shares of Ophthotech would be converted into cash or securities of a Person or a 13D Group not including Novartis or its Affiliates where Persons other than the then-current holders of outstanding shares of Ophthotech would own more than fifty percent (50%) of the securities of the issuer or (B) more than fifty percent (50%) of the then-outstanding shares of Ophthotech would be owned by Persons other than the then-current holders of outstanding shares of Ophthotech, or which would result in a majority of Ophthotech's assets being sold to any Person or 13D Group not including Novartis or its Affiliates; or for the period commencing when Ophthotech publicly announces its determination to pursue (a) the sale or disposition of a majority of the outstanding shares of Ophthotech, (b) the sale or disposition of a majority of Ophthotech's assets or the right to Commercialize Fovista in the Ophthotech Territory or (c) a similar sale or change of control transaction with any party other than Novartis or its affiliates and, in each case, ending upon Ophthotech's determination not to further pursue any such transaction. During the Restricted Period, Novartis agrees not to request Ophthotech to amend or waive the provisions of this Section 10.08 (f) unless it is first contacted by Ophthotech about any of the transactions contemplated by Section 10.8(a). Nothing in this Section 10.08 shall obligate Novartis or its Affiliates to cause Novartis' or its Affiliates' advisors (including financial advisors, attorneys, accountants and consultants) to comply with the terms of this Section 10.08 when acting on their own behalf or on behalf of Persons other than Novartis or its Affiliates.

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Section 10.09 No Implied Wartanties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE PRODUCTS. THE PARTIES AGREE THAT MILESTONE EVENTS AND NET SALES LEVELS SET OUT IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES AS OF THE EFFECTIVE DATE ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS AND ROYALTY OBLIGATIONS IF SUCH MILESTONE EVENTS OR NET SALES LEVELS ARE ACHIEVED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP, MANUFACTURE OR COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.

#### Section 10.10 Indemnification.

- (a) <u>By Ophthotech</u>. Ophthotech shall indemnify, defend and hold harmless Novartis, its Affiliates and their respective directors, officers, employees and agents (collectively, the "Novartis Indemnified Parties"), from, against and in respect of any and all Claims, to the extent arising out of resulting from:
  - (i) any breach of any representation, warranty or covenant made by Ophthotech in this Agreement;
- (ii) any Third Party product liability claim to the extent resulting from Ophthotech's failure to Manufacture API Bulk Drug Substance in accordance with the Supply Agreement;
- (iii) Ophthotech's, or any of its Affiliates', Sublicensees' or contractors' actions in connection with Ophthotech's Development or Manufacture of any Product administered to any human subject prior to the Effective Date;
- (iv) except as otherwise agreed by the Parties pursuant to any Related Agreement entered into after the Effective Date, the Development, Manufacture or Commercialization by Ophthotech, its Affiliates and Sublicensees of any Product Commercialized in the Ophthotech Territory;
- (v) the gross negligence, intentional misconduct or violation of Law by or of Ophthotech or any of the other Ophthotech Indemnified Parties:

provided, however, that in the case of each of clauses (i), (ii), (iii) and (iv) above, Ophthotech shall not be obliged to so indemnify, defend and hold harmless the Novartis Indemnified Parties for any Claims to the extent Novartis has an obligation to indemnify Ophthotech Indemnified Parties under Section 10.10(b) or to the extent such Claims arise out of or result from the gross negligence, willful misconduct or violation of Law of or by Novartis or any of the other Novartis Indemnified Parties.

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- (b) <u>By Novartis</u>. Novartis shall indemnify, defend and hold harmless Ophthotech, its Affiliates and their respective directors, officers, employees and agents (collectively, the "Ophthotech Indemnified Parties"), from, against and in respect of any and all Claims to the extent arising out of or resulting from:
  - (i) any breach of any representation, warranty or covenant made by Novartis in this Agreement;
- (ii) any Claim by Genentech or any of its Affiliates against Ophthotech or as to which Ophthotech becomes a party, to the extent of reasonable legal expenses actually incurred by Ophthotech and judgments awarded against Ophthotech, arising from Novartis' execution and delivery of this Agreement, the performance of Novartis' obligations hereunder or the licenses granted or to be granted by Novartis pursuant to this Agreement conflicting with, violating, breaching or constituting a default under any contractual obligation of Novartis or any of its Affiliates to Genentech or any of its Affiliates;

- (iii) any Third Party product liability claim to the extent resulting from Novartis' failure to Manufacture Products in accordance with the applicable specifications therefor;
- (iv) Novartis', or any of its Affiliates', Sublicensees' or contractors' actions in connection with Novartis' Development or Manufacture of any Novartis Anti-VEGF Product administered to any human subject prior to the Effective Date;
- (v) except as otherwise agreed by the Parties pursuant to any Related Agreement entered into the Parties after the Effective Date, the Development, Manufacture or Commercialization by Novartis, its Affiliates and Sublicensees of any Product Commercialized in the Novartis Territory; or
- (vi) the gross negligence, intentional misconduct or violation of Law by or of Novartis or any of the other Novartis Indemnified Parties:

provided, however, that in the case of each of clauses (i), (ii), (iii), (iv) and (v) above, Novartis shall not be obliged to so indemnify, defend and hold harmless the Ophthotech Indemnified Parties for any Claims to the extent Ophthotech has an obligation to indemnify Novartis Indemnified Parties under Section 10.10(a) or to the extent such Claims arise out of or result from the gross negligence, willful misconduct or violation of Law of or by Ophthotech or any of the other Ophthotech Indemnified Parties.

### (c) <u>Claims for Indemnification</u>.

(i) A Person entitled to indemnification under this Section 10.10 (an "Indemnified Party") shall give prompt written notification to the Party from whom indemnification is sought (the "Indemnifying Party") of any Claim or fact in respect of which the Indemnified Party may base a claim for indemnification hereunder (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party claim as provided in this Section 10.10 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is

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actually prejudiced as a result of such failure to give notice). Such notice (the "Indemnification Claim Notice") shall contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

- (ii) Within [\*\*] days after delivery of such notification, the Indemnifying Party shall assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. If it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an indemnitee harmless from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of suit) incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within [\*\*] days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of clause (vi) below shall govern.
- (iii) The Indemnified Party may participate, but not control, in any such Claim at its own expense; provided that if the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith. The Indemnified Party shall also cooperate with the Indemnifying Party in the defense of such Claim, including by furnishing such records, information and testimony, providing witnesses and attending such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith, providing access during normal business hours to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided, all at the Indemnifying Party's expense.
- (iv) The Indemnifying Party shall keep the Indemnified Party advised of the status of such Claim and the defense thereof and shall consider recommendations made by the Indemnified Party with respect thereto.
- (v) The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall have the right to settle such Claim on any terms the Indemnifying Party chooses; provided, however, that it shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to

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indemnification hereunder or which admits any wrongdoing or responsibility for the Claim on behalf of the Indemnified Party.

(vi) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in clause (ii) above or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request

but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

- Section 10.11 No Consequential or Punitive Damages. NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BREACH OF STATUTORY DUTY OR OTHERWISE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR ANY LOSS OR INJURY TO A PARTY'S PROFITS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.11 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS OR A PARTY'S REMEDIES FOR ANY BREACH BY THE OTHER PARTY OF ARTICLE IX (CONFIDENTIALITY AND PUBLICITY).
- Section 10.12 No Exclusion. Neither Party excludes any liability for death or personal injury caused by its negligence or that of its employees, agents or subcontractors to the extent such exclusion is prohibited by applicable Law.
- Section 10.13 <u>Clarification of [\*\*] Agreement</u>. Ophthotech covenants to Novartis that it will use Commercially Reasonable Efforts to cause the [\*\*] Agreement to be amended to (a) clarify Section [\*\*], and [\*\*] (as defined in this Agreement) under this Agreement as of the [\*\*]. An amendment to the [\*\*] Agreement substantially satisfying the foregoing criteria is herein referred to as the "[\*\*] Agreement Amendment".

### Section 10.14 <u>Use of Commercially Reasonable Efforts Under the [\*\*] Agreement.</u>

(a) Until such time as the [\*\*] Agreement Amendment is confirmed as [\*\*] or through [\*\*], Ophthotech hereby covenants to Novartis that it will comply with its obligations under Section [\*\*] of the [\*\*] Agreement with respect to [\*\*], and shall [\*\*]. In the event that Ophthotech receives [\*\*] pursuant to Section [\*\*] of the [\*\*] Agreement of [\*\*], it shall give Novartis [\*\*]. Following [\*\*], Ophthotech shall take such commercially reasonable steps and actions [\*\*]. In addition, and without limiting the foregoing, Ophthotech shall allow Novartis to

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- [\*\*]. Without limiting the generality of the foregoing, Ophthotech shall take [\*\*]. Notwithstanding ARTICLE [\*\*] of this Agreement, Novartis shall, [\*\*] under Section 10.13 and this Section 10.14.
- (b) Ophthotech shall indemnify Novartis against all reasonable costs and expenses incurred by Novartis in curing any such alleged breach on behalf of Ophthotech to the extent such alleged breach is not the result of a failure or alleged failure by Novartis to exercise Commercially Reasonable Efforts (as defined in the [\*\*] Agreement) with respect to the Major Market (as defined in the [\*\*] Agreement), and Novartis shall be entitled to offset any such indemnifiable costs and expenses (to the extent not paid or reimbursed by Ophthotech) against any amount payable hereunder by Novartis to Ophthotech. Novartis' rights and Ophthotech's obligations pursuant to this Section 10.14 shall terminate and not apply to any breach or alleged breach by Ophthotech of its obligations under Section 3.3(b) of the [\*\*] Agreement after the [\*\*] Agreement Amendment is confirmed as satisfactory by Novartis as set forth in Section 13.14 below.

# ARTICLE XI TERM AND TERMINATION

Section 11.01 <u>Term</u>. Unless terminated earlier in accordance with this ARTICLE XI, this Agreement shall remain in force for the period commencing on the Effective Date and ending upon the expiration of the last to expire of the Full Royalty Terms and the Reduced Royalty Terms (the "<u>Term</u>").

# Section 11.02 <u>Termination for Material Breach</u>.

(a) Upon any material breach of this Agreement by a Party (the "Breaching Party."), the other Party (the "Non-Breaching Party.") may give written notice to the breaching Party specifying the claimed particulars of such breach. The Breaching Party shall have a period of [\*\*] days after such notice if such material breach is a breach of a payment obligation or [\*\*] days after such notice in the case of any other material breach in which to cure such breach; provided, however, that if such breach other than a payment breach is capable of being cured and cannot be cured within such [\*\*] day period, and the Breaching Party notifies the Non-Breaching Party within such period that it has initiated actions to cure such breach and thereafter diligently pursues such actions, the Breaching Party shall have such additional period as is reasonable in the circumstances, but in no event longer than [\*\*] days after the end of the original cure period, to cure such breach. If any alleged breach hereunder is disputed pursuant to the dispute resolution process set forth in ARTICLE XII, the cure period shall be suspended for the duration of, and until resolution of, such dispute resolution process. Any termination by any Party under this Section 11.02 and the effects of termination provided in this ARTICLE XI shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. If the Breaching Party fails to cure the breach within the time period set forth above, the Non-Breaching Party shall have the right thereafter to terminate this Agreement effective immediately by giving written notice to the Breaching Party to such effect; provided that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to the Products or elect not to terminate this Agreement.

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(b) If Ophthotech is the Breaching Party and Novartis has the right to terminate this Agreement pursuant to the foregoing clause (a) but elects not to terminate this Agreement pursuant to the foregoing clause (a), (i) Novartis may offset any damages resulting from such material breach that are either agreed between the Parties or established through dispute resolution pursuant to ARTICLE XII against subsequent payment obligations of Novartis to Ophthotech hereunder and (ii) Novartis shall cease to be required to consult with or seek approval from the JOC or the Subcommittees for amendments to the Development Plan or Marketing Plan or to disclose or provide to Ophthotech, directly or indirectly, marketing or branding strategy information; provided that the Parties' obligations to consult and coordinate with one another to the extent reasonably necessary to preserve the value of the Products in the Parties' respective territories on matters such as pharmacovigilance and Manufacturing are preserved. To that extent, the Parties shall negotiate amendments to ARTICLE II reasonably acceptable to Novartis.

Section 11.03 <u>Termination for Insolvency</u>. Each Party shall have the right to terminate this Agreement upon written notice to the other Party if an Insolvency Event occurs with respect to such other Party. In any event when a Party first becomes aware of the likely occurrence of any Insolvency Event in regard to that Party, it shall promptly so notify the other Party in sufficient time to give the other Party sufficient notice to protect its interests under this Agreement.

- Section 11.04 <u>Termination by Ophthotech Relating to Novartis Alternative Anti-PDGF Products</u>. Ophthotech shall have the right to terminate this Agreement as set forth in Section 3.07(g). The effective date of such termination shall be specified by Ophthotech and may be up to two (2) years in the future (unless an alternative longer timeframe is agreed in writing between the Parties).
- Section 11.05 <u>Termination by Novartis for Safety Issues</u>. Novartis may, upon ninety (90) days' prior written notice to Ophthotech, unilaterally terminate this Agreement if (a) a Regulatory Authority or safety data review board for a clinical study of a Product has required termination or suspension of a clinical study of a Product and such termination or suspension can reasonably be expected to have a material adverse effect on the overall Development or Commercialization of Products, (b) Novartis reasonably believes in good faith that termination or suspension of a clinical study of a Product is warranted because of an adverse balance between risk and benefit to the study subjects and such termination or suspension can reasonably be expected to have a material adverse effect on the overall Development or Commercialization of Products, or (c) Novartis reasonably believes in good faith that the continued Commercialization of a marketed Product poses an adverse balance between risk and benefit to patients.
- Section 11.06 <u>Termination for Certain Injunctions or Orders</u>. From the Effective Date up until two years following the first EU Regulatory Approval of a Product, either Party may, upon written notice to the other Party, unilaterally terminate this Agreement if the Parties are prevented in any manner that materially adversely affects the progression of the Development or Commercialization of Product(s) as contemplated in this Agreement for a period of six (6) months or more as a result of any Government Order based on antitrust or competition Law grounds.

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Section 11.07 <u>Termination for Convenience</u>. Novartis shall have the right to terminate this Agreement upon one (1) year's prior written notice to Ophthotech. Following such notice of termination, Ophthotech may elect to accelerate the effective date of such termination to any time earlier than the end of such one (1) year notice period upon written notice to Novartis specifying such earlier termination date; <u>provided that</u> such earlier date is consistent with the orderly wind down set forth in Section 11.10(e)(v).

#### Section 11.08 <u>Termination for Certain Patent Challenges</u>.

- By Ophthotech. Ophthotech shall have the right to terminate this Agreement, effective immediately upon written notice to (a) Novartis, if Novartis or any of its Affiliates or Sublicensees initiates a Challenge or directly or indirectly assists a Third Party in initiating a Challenge. For purposes of this Section 11.08(a), "Challenge" means any challenge to the validity or enforceability of any Patent Right within the Ophthotech IP or Ophthotech Collaboration IP, including any challenge effected by (i) filing a declaratory judgment action in which any such Patent Right is alleged to be invalid or unenforceable, (ii) citing prior art pursuant to 35 U.S.C. §301, filing a request for re-examination of any such Patent Right pursuant to 35 U.S.C. §302 or §311 or provoking or becoming party to an interference with an application for any such Patent Right pursuant to 35 U.S.C. §135, or (iii) filing or commencing any reexamination, opposition, cancellation, nullity or similar proceedings against any such Patent Right in any country, including any such challenge that any Existing Fovista Agreement prohibits Ophthotech or its Affiliates or Sublicensees from initiating or that would give a counterparty to any Existing Fovista Agreement a right to terminate, or otherwise claim a remedy (e.g., claim a higher royalty, if applicable) under, such Existing Fovista Agreement. Notwithstanding any provision in this Agreement to the contrary, Ophthotech shall have no right to terminate this Agreement with respect to any Challenge: (A) which results from compliance by Novartis or any of its Affiliates or Sublicensees with any judicial, legislative or administrative order or request for information that results from the initiation of any Challenge by a Third Party whose challenge is not funded or otherwise supported or suggested in any manner by Novartis or any of its Affiliates or Sublicensees, or by a court, agency or other governmental body having appropriate jurisdiction; or (B) which results from any defense or counterclaim to any legal action brought by Ophthotech or any of its Affiliates against Novartis or any of its Affiliates or Sublicensees for infringement of the Patent Rights that are the subject of the Challenge; provided, however, that Novartis acknowledges and agrees that such actions may result in Ophthotech's and Novartis' loss of rights granted pursuant to the Existing Fovista Agreements, that Ophthotech shall have no liability to Novartis, its Affiliates or Sublicensees as a consequence of any such loss of rights, and that Novartis shall, subject to Section 10.11, be liable to Ophthotech for any and all losses suffered by Ophthotech as a consequence of any such loss of rights.
- (b) <u>By Novartis</u>. Novartis shall have the right to terminate this Agreement, effective immediately upon written notice to Ophthotech, if Ophthotech or any of its Affiliates or Sublicensees initiates a Challenge or directly or indirectly assists a Third Party in initiating a Challenge. For purposes of this Section 11.08(b), "Challenge" means any challenge to the validity or enforceability of any Patent Right within the Novartis IP or Novartis Collaboration IP, including any challenge effected by (i) filing a declaratory judgment action in which any such Patent Right is alleged to be invalid or unenforceable, (ii) citing prior art pursuant to 35 U.S.C.

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§301, filing a request for re-examination of any such Patent Right pursuant to 35 U.S.C. §302 or §311 or provoking or becoming party to an interference with an application for any such Patent Right pursuant to 35 U.S.C. §135, or (iii) filing or commencing any reexamination, opposition, cancellation, nullity or similar proceedings against any such Patent Right in any country. Notwithstanding any provision in this Agreement to the contrary, Novartis shall have no right to terminate this Agreement with respect to any Challenge: (A) which results from compliance by Ophthotech or any of its Affiliates or Sublicensees with any judicial, legislative or administrative order or request for information that results from the initiation of any Challenge by a Third Party whose challenge is not funded or otherwise supported or suggested in any manner by Ophthotech or any of its Affiliates or Sublicensees, or by a court, agency or other governmental body having appropriate jurisdiction; or (B) which results from any defense or counterclaim to any legal action brought by Novartis or any of its Affiliates against Ophthotech or any of its Affiliates or Sublicensees for infringement of the Patent Rights that are the subject of the Challenge.

# Section 11.09 <u>Termination for Change in Control of Ophthotech.</u>

(a) Novartis may, upon six (6) months prior written notice to Ophthotech (or such longer notice as reasonably necessary to conduct an orderly wind down as set forth in Section 11.10(e)(v)) given by Novartis within ninety (90) days following the earliest public announcement of such event, unilaterally terminate this Agreement following an Ophthotech Change in Control.

- (b) If an Ophthotech Change in Control occurs and Novartis has the right to terminate this Agreement pursuant to the foregoing clause (a) but elects not to terminate this Agreement pursuant to the foregoing clause (a), then upon Novartis' written request to Ophthotech within ninety (90) days following the earliest public announcement of such Ophthotech Change in Control, Novartis shall cease to be required to consult with or seek approval from the JOC or the Subcommittees for amendments to the Development Plan or Marketing Plan or to disclose or provide to Ophthotech, directly or indirectly, information regarding Commercialization activities or strategy; provided that the Parties shall consult and coordinate with one another to the extent reasonably necessary to preserve the value of the Products in the Parties' respective territories on matters such as pharmacovigilance and Manufacturing. To that extent, the Parties shall negotiate in good faith amendments to ARTICLE II of this Agreement reasonably acceptable to Novartis.
- Section 11.10 <u>Effects of Termination</u>. In the event of any termination of this Agreement pursuant to Sections 11.02 to 11.09, inclusive, the following provisions of this Section 11.10 shall apply except as specified below:
- (a) <u>Clinical Studies</u>. Novartis shall wind down, or if requested by Ophthotech, transition to Ophthotech or its designee, any clinical study of a Product as to which Novartis is the regulatory sponsor that is ongoing as of the effective date of termination to the extent such clinical study was being carried out by Novartis or funded by Novartis immediately prior to termination of this Agreement.
- (b) <u>Combination Products in the Novartis Territory.</u> To the minimum extent and for the minimum duration required by Law, if such termination occurs after the commercial

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launch of a Combination Product in the Novartis Territory, the Parties shall cooperate to continue to make such Combination Product commercially available in the Novartis Territory, and Novartis shall continue to pay Ophthotech all royalties, sales milestones and other API Supply costs under the Supply Agreement that would have become payable under this Agreement or any Related Agreement in the absence of such termination based on such continuing Commercialization and if applicable, Manufacturing of such Combination Product following such termination. The Supply Agreement shall also apply to the ongoing API Supply requirements to enable Novartis to comply with this Section.

- (c) <u>Standalone Product</u>. With respect to Standalone Products in the Novartis Territory:
- (i) Novartis shall as promptly as commercially practicable transfer on an as-is basis to Ophthotech or Ophthotech's designee (A) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and pricing and reimbursement approvals) relating to the Development, Manufacture or Commercialization of the Standalone Product, to the extent permitted under applicable Law, and Novartis shall reasonably cooperate, at no additional out-of-pocket cost to Novartis, with requests by Ophthotech for assistance necessary to facilitate Ophthotech's assumption of regulatory responsibilities for the Standalone Product in the applicable countries in which direct transfer is not permitted, and (B) copies of all data, reports, records and materials in Novartis' possession or control relating to the Development and Manufacture of the Standalone Product, including all non-clinical and clinical data relating to the Standalone Product, and, with respect to Commercialization of the Standalone Product, copies of all data, reports, records and materials in Novartis' possession or control reasonably necessary to effect an orderly transition of Commercialization of the Standalone Product; and Novartis may keep one copy of the items described in the foregoing clauses (A) and (B), which it may retain in its confidential files for archive purposes;
- (ii) In the event of termination by Ophthotech pursuant to Section 11.02, Section 11.04 or Section 11.08, or by Novartis pursuant to Section 11.07, Novartis shall, at Ophthotech's option, supply Ophthotech's requirements for the Standalone Product to Ophthotech in the Novartis Territory at a price of [\*\*] percent ([\*\*]%) of the Manufacturing Cost thereof, until such time as all Regulatory Approvals for the Standalone Product in the Novartis Territory have been transferred to Ophthotech or Ophthotech's designee, Ophthotech has obtained all necessary Manufacturing approvals and Ophthotech has procured or developed its own source of Standalone Product supply; provided, however, that Novartis shall not be obligated to supply the Standalone Product to Ophthotech for longer than [\*\*] years following termination of this Agreement and that Ophthotech will use its best efforts to ensure that all relevant transfers and approvals occur in the shortest possible time;
- (iii) the licenses granted to Novartis in Section 3.01 shall terminate (except to the extent necessary to enable Novartis to perform its obligations under the immediately preceding clause (ii));
- (iv) Novartis shall promptly provide Ophthotech with a summary of all Third Party agreements relating to the Development, Manufacture or Commercialization of the

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Standalone Product to which Novartis is a party and shall transfer to Ophthotech any such Third Party agreements solely relating to the Development, Manufacture or Commercialization of the Standalone Product that Ophthotech requests be assigned, to the extent such transfer is permitted thereunder; with respect to each agreement relating to the Development, Manufacture or Commercialization of the Standalone Product that is not transferred to Ophthotech, at Ophthotech's request, Novartis shall reasonably facilitate a direct introduction between Ophthotech and the Third Party counterparty to such agreement;

- (v) Novartis shall grant to Ophthotech a non-exclusive, irrevocable, perpetual, royalty-free (except as set forth in the following proviso) right and license, with right to grant sublicenses, under all Intellectual Property used by Novartis in connection with the Standalone Product prior to the effective date of termination and Controlled by Novartis as of the effective date of termination, to Develop, Manufacture and Commercialize the Standalone Product in the Field for the Novartis Territory; provided, however, that such license shall only extend to Third Party IP licensed by Novartis if Ophthotech notifies Novartis in writing that Ophthotech elects to receive a sublicense under such Third Party IP, and in such case Ophthotech shall pay to Novartis the amounts, if any, that become payable to applicable Third Party licensors under any such license agreements between Novartis and such Third Party licensor as a result of Ophthotech's exercise of rights sublicensed to Ophthotech pursuant to the license granted in this clause (v), following receipt from Novartis of documentation evidencing such payment obligations;
- (vi) Novartis shall transfer to Ophthotech the global safety database for the Standalone Product and, to the extent there are ongoing pharmacovigilance obligations under Section 11.10(b), the Parties will cooperate to fulfill any such obligations; and

- (vii) Novartis shall execute all documents and take all such further actions as may be reasonably requested by Ophthotech in order to give effect to the foregoing clauses (i) through (vi).
- (d) <u>Certain Related Agreements</u>. Any agreement that Novartis and Ophthotech have entered into prior to the effective date of termination pursuant to Section 3.01(f), Section 3.03, Section 3.04(c), Section 3.06(c)(ii), Section 3.07(e), Section 3.07(g)(ii), Section 5.09 or Section 6.04 shall survive such termination in accordance with its terms.

### (e) Other Effects of Termination.

- (i) <u>Alternative Anti-PDGF Product Rights</u>. If this Agreement terminated by Novartis pursuant to Section 11.05, 11.07 or 11.09 or by Ophthotech pursuant to Section 11.02, 11.03 or 11.08, then, except as otherwise provided in Section 3.07(g), Ophthotech's rights to receive royalties relating to the Novartis Alternative Anti-PDGF Products under Section 3.07(g)(iii) shall survive such termination, in accordance with its terms, whether the applicable Novartis Alternative Anti-PDGF Product is first Commercialized prior to or after such termination.
- (ii) Other Effect of Termination by Ophthotech Under Section 11.04. If this Agreement is terminated by Ophthotech under Section 11.04, then, except as otherwise

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provided in Section 3.07(g), Novartis shall pay the following amounts to Ophthotech with respect to Novartis Alternative Anti-PDGF Products following termination: (A) [\*\*] percent ([\*\*]%) of the aggregate amount of milestone payments under Section 7.02(a) and Section 7.02(b) that were not earned prior to such termination, which shall become payable to Ophthotech upon the [\*\*] and (B) [\*\*], as described in this Section 11.10(e)(ii) below. The [\*\*].

- (iii) Other Effect of Termination by Ophthotech Under Section 11.06. If Ophthotech terminates this Agreement pursuant to Section 11.06 (A) within [\*\*] after the Effective Date, Ophthotech shall, within [\*\*] days following the effective date of such termination, refund to Novartis one hundred twenty-five million U.S. dollars (\$125,000,000) of the amount paid by Novartis to Ophthotech pursuant to Section 7.01, or (B) following the first year after the Effective Date, Ophthotech shall, within [\*\*] days following the effective date of such termination, refund to Novartis two hundred million U.S. dollars (\$200,000,000) of the amount paid by Novartis to Ophthotech pursuant to Section 7.01, except that Ophthotech may extend such [\*\*] day period to up to the earliest of receipt of the refund from the relevant tax authorities for any portion of such amounts that were paid in taxes or [\*\*] years after the notice of termination.
- (iv) <u>Survival of Novartis Licenses</u>. Novartis' licenses hereunder shall survive to the extent necessary for Novartis to perform its post-termination obligations under this ARTICLE XI.
- (v) <u>Orderly Wind Down of Development and Commercialization</u>. Subject to Section 11.10(b) and Section 11.10(c), the Parties shall agree upon an orderly wind down of Development and Commercialization activities hereunder for terminated Products (including those activities being performed by their Affiliates, Sublicensees or Third Party contractors) and each Party shall make all payments due and owing to one another and to Third Parties.
- Section 11.11 Return of Confidential Information. Within [\*\*] days following the expiration or termination of this Agreement, except to the extent and for so long as a Party retains license rights under this Agreement, each Party shall deliver to the other Party, or at the delivering Party's option destroy, any and all Confidential Information of the other Party in its possession, except for one copy which may be retained in its confidential files for archive purposes and subject to any copies remaining on its standard computer back-up devices (which copies the Party agrees not to access after termination).
- Section 11.12 <u>Survival</u>. In the event of any expiration or termination of this Agreement, (a) all financial obligations under ARTICLE IV, ARTICLE VII and ARTICLE VIII that have accrued as of the effective date of such expiration or termination, whether or not they have become due, shall remain in effect, and (b) the provisions set forth in ARTICLE I, ARTICLE IX (except for Sections 9.05 and 9.06), ARTICLE XII and ARTICLE XIII, Section 8.01, Section 8.02 (solely with respect to Joint Patent Rights), Section 10.10, Section 10.11, Section 10.12, Section 11.10, Section 11.11, this Section 11.12, and [\*\*], the licenses granted to Ophthotech in Section 3.02 and any license then in effect under Section 3.03(b) or Section 3.04(b), shall survive.

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# ARTICLE XII DISPUTE RESOLUTION

Section 12.01 <u>Legal Disputes</u>. In the event of any dispute or disagreement regarding the formation, existence, validity, enforceability, performance, interpretation, breach or termination of this Agreement or any Related Agreement or regarding the scope, validity, infringement or enforceability of any Patent Right and anti-trust or competition law matters under this Agreement (all such matters, "Legal Disputes") either Party may refer the Legal Dispute to the Executive Officers for resolution. If after discussing the matter in good faith and attempting to find a mutually satisfactory resolution to the Legal Dispute, the Executive Officers fail to come to consensus within [\*\*] Business Days after the date on which the Legal Dispute is referred to the Executive Officers (unless a longer period is agreed to in writing by the Executive Officers), the Legal Dispute shall be resolved pursuant to arbitration under Section 12.02 of this Agreement.

# Section 12.02 Arbitration.

(a) Any Legal Dispute (to the extent that not resolved pursuant to Section 12.01 above) and any Non-Casting Vote Matter (to the extent not resolved pursuant to Section 2.08(d)) shall be finally resolved under the Rules of Arbitration of the International Chamber of Commerce in force at the date of the request for arbitration is submitted (except where such rules conflict with the provisions of this Section 12.02, in which event the provisions of this Section 12.02 shall govern) by three (3) arbitrators having pharmaceutical industry experience appointed in accordance with such rules. The place of the

arbitration shall be New York City, New York, United States. The language of the arbitration shall be English. At any time, a Party may seek or obtain preliminary, interim or conservatory measures from the arbitrators or from a court. The arbitrators shall use all reasonable efforts to complete the arbitration proceedings and render an award within [\*\*] months after the last arbitrator is appointed. Judgment on the arbitration award may be entered in any court having jurisdiction.

- Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees or arbitration, unless in each case the arbitrators agree otherwise, which they are hereby empowered, authorized and instructed to do if they determine that to be fair and appropriate.
- Except to the extent necessary to confirm an award or as may be required by law, regulation, or the requirement of any exchange on which a Party's shares are traded, neither Party shall disclose the existence, content or results of an arbitration under this Agreement without the prior written consent of the other Party.

### ARTICLE XIII MISCELLANEOUS

Choice of Law. This Agreement shall be governed by and interpreted under, and any arbitration in accordance with Section 12.02 shall apply, the laws of the State of New York, United States, excluding: (a) any provision thereof that would apply the law of any other jurisdiction; (b) the United Nations Conventions on Contracts for the International Sale of

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Goods; (c) the 1974 Convention on the Limitation Period in the International Sale of Goods (the "1974 Convention"); and (d) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.

Section 13.02 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 13.02 and shall be: (a) delivered personally; (b) transmitted by facsimile; or (c) sent via a reputable international overnight delivery service. Any such notice, instruction or communication shall be deemed to have been delivered (i) upon receipt if delivered by hand or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission), provided that an original document is sent via an internationally recognized overnight delivery service (receipt requested), or (ii) one (1) Business Day after it is sent via a reputable international overnight delivery service.

If to Ophthotech: Ophthotech Corporation

One Penn Plaza, 19th Floor New York, NY 10119

U.S.A.

Attention: Chief Executive Officer Facsimile No.: +1 212 845 8250

With copies to: **Ophthotech Corporation** 

One Penn Plaza, 19th Floor New York, NY 10119

U.S.A.

Attention: General Counsel Facsimile No.: +1 212 845 8250

WilmerHale LLP and.

> 60 State Street Boston, MA 02109

U.S.A.

Attention: Steven D. Barrett, Esq. Facsimile No.: +1 617 526 5000

Novartis Pharma AG If to Novartis:

Lichtstrasse 35 CH-4056 Basel Switzerland

Attention: Global Head of BD&L Facsimile No.: +41 61 324 2100

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With a copy to: Novartis Pharma AG

Lichtstrasse 35 CH-4056 Basel Switzerland

Attention: Global Legal, Ophthalmology

Facsimile No.: +41 61 324 7399

Section 13.03 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable, good faith efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of the Severed Clause and this Agreement.

Section 13.04 Integration. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral. Notwithstanding the authority granted to the Subcommittees under this Agreement, this Agreement may be amended only in writing signed by properly authorized representatives of each of Ophthotech and Novartis. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto or any Related Agreement, the substantive provision of this Agreement shall prevail.

Section 13.05 <u>Independent Contractors; No Agency.</u> Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party, including the Ophthotech Representatives, shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Ophthotech and Novartis, or to constitute one as the agent of the other. Moreover, each Party agrees not to construct this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes.

Section 13.06 <u>Assignment; Successors.</u> Neither Party will assign, transfer or novate this Agreement without the prior written consent of the other Party, except assignment or transfer will be permitted by notice in writing, and without the prior written consent of the other Party, to: (a) any of the assigning Party's Affiliate; or (b) a purchaser of a substantial part of a Party's assets or business relating to the subject matter of this Agreement; <u>provided that</u> nothing in this Section 13.06 shall limit in any way Novartis' rights with respect to a Change of Control of Ophthotech as set forth in Section 11.09. This Agreement shall be binding upon, and shall inure to the benefit of, all successors and permitted assigns. Any permitted assignee will assume all

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obligations of its assignor under this Agreement. Any assignment, transfer or novation made in violation of this Section 13.06 shall be wholly void and invalid, the assignee, transferee or successor shall acquire no rights whatsoever, and the non-assigning Party shall not recognize, nor shall it be required to recognize, the assignment, transfer or novation.

Section 13.07 <u>Performance by Other Persons</u>. Subject to Section 3.01(f), each Party may exercise its rights and perform its obligations under this Agreement itself or through any of its Affiliates or permitted sub-licensees, and may subcontract its Development, Manufacturing and Commercialization activities hereunder as it deems appropriate without the other Party's consent (including to distributors or wholesalers in the ordinary course of business). Each Party shall be responsible for the performance and compliance with this Agreement of its Affiliates, permitted sub-licensees, authorized agents and subcontractors.

Section 13.08 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to any natural disaster, explosion, fire, flood, act of nature (including tornadoes, thunderstorms, earthquakes, typhoons, hurricanes, and tsunamis), actions of Governmental Authorities, war, hostilities between nations, civil commotions, terrorism, riots, embargo, losses or shortages of power, national industry strikes, lockouts, labor stoppage, sabotage, substance or material shortages, damage to or loss of product in transit, events caused by reason of Laws of any Regulatory Authority, events caused by acts or omissions of a Third Party, or any other cause reasonably beyond the control of such Party. The Party affected by such force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its good faith estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than ninety (90) days, the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

Section 13.09 No Third Party Beneficiaries. Except for Indemnified Parties as set forth in Section 10.10, this Agreement shall not be construed as conferring any rights or remedies upon any Person other than the Parties and their respective successors and permitted assigns.

Section 13.10 <u>Execution in Counterparts; Facsimile Signatures</u>. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided electronically by PDF or facsimile transmission shall be deemed to be original signatures.

Section 13.11 <u>English Language</u>. This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

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Section 13.12 <u>Expenses.</u> Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this Agreement.

Section 13.13 <u>Cumulative Remedies.</u> No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

Section 13.14 Restrictions on Ophthotech's Rights. Notwithstanding anything to the contrary in this Agreement, Ophthotech's rights set forth in Sections [\*\*] to the extent that the Requesting Party is Ophthotech, of this Agreement shall not be effective, and Ophthotech shall not be entitled to exercise any option contained therein, unless and until Novartis shall have received a fully executed copy of the [\*\*] Agreement Amendment and Novartis has notified

Ophthotech either that (a) [\*\*]. If Ophthotech obtains an amendment to the [\*\*] Agreement that substantially meets the criteria set forth in Section 10.13, Novartis shall not [\*\*]. For the avoidance of doubt, the Ophthotech rights set forth above shall not be effective and [\*\*] unless and until an [\*\*] Agreement Amendment is [\*\*] pursuant to this Section 13.14 or, [\*\*].

[Signature page follows]

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IN WITNESS WHEREOF, Ophthotech and Novartis have caused this Agreement to be duly executed by their authorized representatives under seal, in duplicate on the dates written herein below.

#### OPHTHOTECH CORPORATION

By: /s/ David R. Guyer

Title: Chief Executive Officer

Date: May 19, 2014

### NOVARTIS PHARMA AG

By: /s/ Dr. Markus Rohrwild

Title: Global BF Head Ophthalmics

Date: 19 May 2014

By: /s/ Lena Moran-Adams

Title: Senior Legal Counsel Date: 19 May 2014

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# **EXHIBIT A**

#### OPHTHOTECH PRODUCT PATENT RIGHTS AND OPHTHOTECH IP AGREEMENTS

A. Ophthotech Fovista Non-US Patents and Patent Applications

Country [**]	Title	Filing Date	Application No.	Publication No.	Patent No.	Grant Date	Assignee
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 15 pages were omitted. [\*\*]

B. Enzon and Nektar Non-US Patents and Patent Applications

Country	Title	Application No.	Filing Date	Patent No.	Grant Date
			[**]		
[**]	[**]	[**]	[**]	[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 5 pages were omitted. [\*\*]

C. Agreements relating to the Ophthotech IP

[\*\*]

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# EXHIBIT B

# **EXISTING FOVISTA CLINICAL PROGRAM**

1. The three (3) Phase III Clinical Studies (OPH1002, OPH1003 and OPH1004) with an aggregate of up to approximately 1866 patients treated for up to two (2) years

Three (3) planned Phase II Clinical Studies with an aggregate of up to [**] patients treated for up to [**], which may include (a) an anti-fibrosis study in wet AMD, (b) a reduction of treatment burden study in wet AMD, and (c) an anti-VEGF treatment failure study in wet AMD
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EXHIBIT C
INITIAL DEVELOPMENT PLAN
Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 4 pages were omitted. [**]
D-1
EXHIBIT D
FOVISTA DESCRIPTION
Fovista (pegpleranib sodium, X01E)
**].
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<u>EXHIBIT E</u>
RTH258 DESCRIPTION
RTH258 [**]
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EXHIBIT F
<u>INITIAL MARKETING PLAN CONTENTS</u>
**]
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EXHIBIT G
QUID PRODUCTS **1
**] G-1
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EVHIDITH
EXHIBIT H  INVOICE FOR UPFRONT PAYMENT
See following page.
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#### -INVOICE-

May 19, 2014 Invoice # 201400001
Payment Terms: Upon Receipt

Novartis Pharma AG Switzerland

In connection with Section 7.01 of the Development and Commercialization Agreement by and between Ophthotech Corporation and Novartis Pharma AG, dated May 19, 2014, please remit the following:

Upfront Payment payable within [\*\*] of execution of contract

\$200,000,000.00 (USD)

Wire Instructions:

Bank: [\*\*]
Bank Address: [\*\*]

Account #: [\*\*]
ABA/Routing # [\*\*]
SWIFT Code: [\*\*]

Credit: Ophthotech Corporation

If you have any questions, please feel free to contact Tom Biancardi at [\*\*].

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# EXHIBIT I

#### PERMITTED DISCLOSURES

Fact of an Issuance of any positive or negative opinion (not the opinion itself) by the Committee for Medicinal Products for Human Use (CHMP) regarding any Product

Filings and acceptance of filings for Regulatory Approval of the Products in the EU, any Major European Country or Japan

Regulatory Approvals in the EU, any Major European Country or Japan

Completion of clinical studies and top line results thereof

Completion of patient enrollment for the Existing Fovista Clinical Program

Reimbursement and pricing approvals by governmental agencies in any Major European Country or Japan

Development and Commercialization milestone achievements

Launch in any Major European Country or Japan

Announcement of data at scientific or financial forums, subject to the provisions of Section 9.06

Regulatory actions that could be material for the Ophthotech Territory

Royalties earned outside of the Ophthotech Territory in quarterly earnings releases and calls

Announcements of publications

Announcements of issued patents and other disclosures relating to Ophthotech's Intellectual Property

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### **EXHIBIT J**

# COMMERCIALIZATION PERFORMANCE STANDARDS

To be amended in accordance with Section 5.02(b).

#### **EXHIBIT K**

#### INITIAL PRESS RELEASE



# Ophthotech Corporation Enters into Ex-US Licensing and Commercialization Agreement for Fovista® with Novartis

- Ophthotech to Potentially Receive Over \$1 Billion, Inclusive of \$330 Million in an Upfront Fee (\$200 Million) and Near-term Enrollment Milestones
  (\$130 Million), Not Including Future Royalties
  - Ophthotech Grants Ex-US Commercialization Rights to Fovista® while Retaining Sole US Commercial Rights -
    - Ophthotech to Host Conference Call Today at 5:00 p.m. Eastern Time -

New York, NY - May, 19, 2014 — Ophthotech Corporation (Nasdaq: OPHT) announced today that the Company has entered into an ex-US licensing and commercialization agreement with Novartis Pharmaceuticals focused on the treatment of wet age-related macular degeneration (AMD). Under the agreement, Ophthotech grants Novartis exclusive rights to commercialize Ophthotech's lead product candidate, Fovista®, in markets outside the United States while Ophthotech retains sole rights to commercialize Fovista® in the United States. Potential payments to Ophthotech under the agreement could total over \$1 billion in upfront and milestone payments, not including future royalties. Fovista® is the most advanced anti-PDGF agent in development for the treatment of wet AMD and, if approved, is expected to be first to market in this class of therapies for wet AMD.

Ophthotech will continue to lead the global Fovista® Phase 3 wet AMD pivotal clinical program which is expected to have initial, topline data available in 2016. Ophthotech will continue its lead role in the potential registration of Fovista® in the United States, while Ophthotech and Novartis will collaborate to seek regulatory approvals outside the United States.

This collaboration continues the Fovista® development strategy to remain agnostic with respect to the choice of the anti-VEGF agent administered in combination with Fovista®. Separate injections of the anti-VEGF agent and Fovista® would allow physicians to choose their preferred anti-VEGF agent for the combination therapy. The collaboration also provides for the potential development of a fixed combination delivery of a co-formulation of Fovista® with a Novartis proprietary anti-VEGF product which would result in additional flexibility for physicians. Novartis will also seek to develop and commercialize alternative innovative delivery technologies such as a Fovista® pre-filled syringe as part of this collaboration.

"As one of the largest ex-US partnering deals ever in the biotechnology industry, this collaboration with Novartis is potentially transformational for Ophthotech," stated David R. Guyer, M.D., Chief Executive Officer and Chairman of the Board of Ophthotech. "This

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agreement represents an important achievement for the Company as we continue to execute on a strategy to deliver science-driven retinal products and offer physicians multiple treatment options to improve patient outcome. The collaboration also supports our previously stated plan to partner Fovista® outside the United States while we retain sole commercialization rights to Fovista® in the United States. The collaboration not only provides a substantial strategic and financial benefit to Ophthotech, it also begins to put in place essential elements designed to expand the reach of Fovista® outside the United States, following potential regulatory approvals."

Under the financial terms of the agreement:

- · Ophthotech to potentially receive over \$1 billion in upfront and milestone payments during the course of the collaboration, not including future royalties.
  - · Ophthotech could receive immediate payment and near-term milestones totaling up to \$330 million, including an upfront fee of \$200 million and Fovista® Phase 3 enrollment-based milestones of up to \$130 million.
  - · Ophthotech is eligible to receive contingent future ex-US marketing approval milestones totaling up to \$300 million and ex-US sales milestones up to \$400 million.
- · Ophthotech is entitled to receive royalties on ex-US Fovista® sales.

WilmerHale acted as legal counsel for Ophthotech in connection with the transaction.

# Ophthotech Conference Call / Web Cast Information

Ophthotech's management will host a conference call and audio web cast to discuss this announcement. The call is scheduled for May 19, 2014, at 5:00 p.m., Eastern Time. To participate in this conference call, dial 1-888-427-9411 (USA) or 719-325-2354 (International), passcode 9388136 shortly before 5:00 p.m. Eastern Time. A replay of the call will be available from approximately two hours following the live call for two weeks. The replay number is 1-888-203-1112 (USA) or 719-457-0820 (International), passcode 9388136. The audio webcast can be accessed at www.ophthotech.com.

# About the Fovista® Phase 3 Program

The Fovista® Phase 3 program consists of three clinical trials to evaluate the safety and efficacy of Fovista® (anti-PDGF) therapy, which Ophthotech is developing for use in combination with anti-VEGF drugs for the treatment of wet age-related macular degeneration. The Company expects to enroll up to 1,866 patients in the three trials in more than 225 centers worldwide and to have initial, topline data from the Fovista® Phase 3 clinical program available in 2016.

# **About Wet AMD**

Age-related macular degeneration is a disease characterized by progressive degenerative abnormalities in the macula of the eye, a small area in the central portion of the retina. Age-related macular degeneration is classified into one of two general subgroups: the "dry" (non-neovascular) form of the disease; and the "wet" (exudative or neovascular) form of the disease. The "dry" form of AMD is characterized by a slow degeneration of the macula resulting in atrophy of the central retina, with gradual vision loss over a period of years. By contrast, "wet" AMD typically causes sudden, often substantial, loss of central vision and is responsible for most cases of severe loss of visual acuity in this disease. Age-related macular degeneration is characteristically a disease of individuals aged 50 years or older, and is the leading cause of blindness in developed countries around the world.

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#### **About Ophthotech Corporation**

Ophthotech is a biopharmaceutical company specializing in the development of novel therapeutics to treat diseases of the eye, with a focus on developing innovative therapies for age-related macular degeneration (AMD). Ophthotech's most advanced product candidate, Fovista® anti-PDGF therapy, is in Phase 3 clinical trials for use in combination with anti-VEGF drugs that represent the standard of care for the treatment of wet AMD. Ophthotech's second product candidate Zimura<sup>TM</sup>, an inhibitor of complement factor C5, is being developed for the treatment of dry and wet forms of AMD. For more information, please visit www.ophthotech.com.

#### Forward-looking Statements

Any statements in this press release about Ophthotech's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about Ophthotech's strategy, future operations and future expectations and plans and prospects for Ophthotech, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, Ophthotech's forward looking statements include statements about the anticipated receipt of payments under its licensing and commercialization agreement with Novartis, the conduct of the Fovista Phase 3 clinical program, including obtaining initial, top-line data from the Fovista Phase 3 clinical program and seeking marketing approval for Fovista, the potential of Fovista as a wet AMD combination therapy and the development of new drug-delivery technologies. Such forward-looking statements involve substantial risks and uncertainties that could cause Ophthotech's clinical development programs, future results, performance or achievements to differ significantly from those express or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and conduct of clinical trials, including Ophthotech's ability to satisfy certain patient enrollment milestones, availability of data from clinical trials, expectations for regulatory approvals or other actions, including the receipt of regulatory approvals outside of the United States which would trigger the receipt of certain milestone payments, Ophthotech's ability to comply with its obligations under and otherwise maintain its licensing and commercialization agreement with Novartis and other factors discussed in the "Risk Factors" section conta

# **Ophthotech Contacts**

**Investors** 

Kathy Galante
Ophthotech Corporation
Vice President, Investor Relations and Corporate Communications
212-845-8231
kathy.galante@ophthotech.com

#### Media

Jarrod Aldom SmithSolve LLC on behalf of Ophthotech Corporation 973-442-1555 ext. 112 jarrod.aldom@smithsolve.com

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#### EXHIBIT L

NOVARTIS ALTERNATIVE ANTI-PDGF PRODUCT ACTIVITIES

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#### **CERTIFICATIONS**

- I, David R. Guyer, M.D., certify that:
  - 1. I have reviewed this Quarterly Report on Form 10-Q of Ophthotech Corporation;
- 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)) 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) 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
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2014 By: /s/ David R. Guyer

David R. Guyer, M.D. Chief Executive Officer (Principal Executive Officer)

#### **CERTIFICATIONS**

#### I, Bruce A. Peacock, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Ophthotech Corporation;
- 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)) 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) 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
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2014 By: /s/ Bruce A. Peacock

Bruce A. Peacock Chief Financial and Business Officer (Principal Financial Officer)

#### **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 Ophthotech Corporation (the "Company") for the period ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David R. Guyer, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, 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: August 6, 2014 By: /s/ David R. Guyer

David R. Guyer M.D. Chief Executive Officer (Principal Executive Officer)

#### **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 Ophthotech Corporation (the "Company") for the period ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Bruce A. Peacock, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, 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: August 6, 2014 By: /s/ Bruce A. Peacock

Bruce A. Peacock Chief Financial and Business Officer (Principal Financial Officer)

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