

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 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 **March 31, 2015**

OR

- ( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-19034

**REGENERON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

New York  
(State or other jurisdiction of  
incorporation or organization)

13-3444607  
(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York  
(Address of principal executive offices)

10591-6707  
(Zip Code)

(914) 847-7000  
(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  No

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  No

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  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) 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  No

Number of shares outstanding of each of the registrant's classes of common stock as of April 16, 2015:

Class of Common Stock	Number of Shares
Class A Stock, \$.001 par value	1,971,868
Common Stock, \$.001 par value	101,305,623

**REGENERON PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
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"ARCALYST<sup>®</sup>", "EYLEA<sup>®</sup>", "ZALTRAP<sup>®</sup>", "VelocImmune<sup>®</sup>", "VelociGene<sup>®</sup>", "VelociMouse<sup>®</sup>", "VelociMab<sup>®</sup>", and "VelociSuite<sup>®</sup>" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.

**PART I. FINANCIAL INFORMATION**
**ITEM 1. FINANCIAL STATEMENTS**

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**  
*(In thousands, except share data)*

	March 31, 2015	December 31, 2014
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 507,907	\$ 648,719
Marketable securities	234,257	251,761
Accounts receivable - trade, net	1,015,962	739,379
Accounts receivable from Sanofi	159,444	121,058
Accounts receivable from Bayer HealthCare	163,056	156,962
Inventories	133,863	128,861
Deferred tax assets	62,126	49,235
Prepaid expenses and other current assets	34,099	71,486
<b>Total current assets</b>	<b>2,310,714</b>	<b>2,167,461</b>
Marketable securities	483,305	460,154
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	1,110,597	974,309
Deferred tax assets	289,484	289,021
Other assets	4,473	3,034
<b>Total assets</b>	<b>\$ 4,198,573</b>	<b>\$ 3,893,979</b>
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 462,762	\$ 483,489
Deferred revenue from Sanofi, current portion	19,342	15,927
Deferred revenue - other, current portion	51,845	58,098
Other current liabilities	2,185	97,146
<b>Total current liabilities</b>	<b>536,134</b>	<b>654,660</b>
Deferred revenue from Sanofi	48,656	72,367
Deferred revenue - other	114,318	103,909
Facility lease obligations	328,394	310,938
Convertible senior notes	144,082	146,773
Other long-term liabilities	55,559	40,855
<b>Total liabilities</b>	<b>1,227,143</b>	<b>1,329,502</b>
<b>Stockholders' equity:</b>		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,971,868 in 2015 and 1,973,368 in 2014	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; shares issued - 103,418,736 in 2015 and 102,475,154 in 2014	103	102
Additional paid-in capital	2,812,573	2,465,008
Retained earnings	292,665	216,644
Accumulated other comprehensive income	47,904	52,251
Treasury stock, at cost; 2,163,980 shares in 2015 and 2,017,732 in 2014	(181,817)	(169,530)
<b>Total stockholders' equity</b>	<b>2,971,430</b>	<b>2,564,477</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 4,198,573</b>	<b>\$ 3,893,979</b>

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

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME**  
**(Unaudited)**  
*(In thousands, except per share data)*

	Three Months Ended March 31,	
	2015	2014
<b>Statements of Operations</b>		
Revenues:		
Net product sales	\$ 544,573	\$ 362,378
Sanofi collaboration revenue	173,356	130,508
Bayer HealthCare collaboration revenue	123,846	125,312
Technology licensing and other revenue	27,837	7,542
	<u>869,612</u>	<u>625,740</u>
Expenses:		
Research and development	343,113	287,379
Selling, general, and administrative	158,991	103,227
Cost of goods sold	42,570	27,473
Cost of collaboration and contract manufacturing	41,385	16,099
	<u>586,059</u>	<u>434,178</u>
Income from operations	283,553	191,562
Other income (expense):		
Investment and other income	81	937
Interest expense	(6,169)	(11,613)
Loss on extinguishment of debt	(942)	—
	<u>(7,030)</u>	<u>(10,676)</u>
Income before income taxes	276,523	180,886
Income tax expense	(200,502)	(112,581)
Net income	<u>\$ 76,021</u>	<u>\$ 68,305</u>
Net income per share - basic	\$ 0.74	\$ 0.69
Net income per share - diluted	\$ 0.66	\$ 0.61
Weighted average shares outstanding - basic	102,227	98,709
Weighted average shares outstanding - diluted	114,519	112,151
<b>Statements of Comprehensive Income</b>		
Net income	\$ 76,021	\$ 68,305
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable securities, net of tax	(4,347)	2,653
Comprehensive income	<u>\$ 71,674</u>	<u>\$ 70,958</u>

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

**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**  
*(In thousands)*

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 76,021	\$ 68,305
<b>Adjustments to reconcile net income to net cash (used in) provided by operating activities:</b>		
Depreciation and amortization	16,027	11,530
Non-cash compensation expense	103,759	75,785
Non-cash interest expense	2,358	5,916
Loss on extinguishment of debt	942	—
Other non-cash charges and expenses, net	6,006	3,761
Deferred taxes	(10,888)	(5,761)
<b>Changes in assets and liabilities:</b>		
Increase in Sanofi, Bayer HealthCare, and trade accounts receivable	(321,063)	(92,529)
Increase in inventories	(5,932)	(15,550)
Decrease (increase) in prepaid expenses and other assets	35,874	(20,898)
(Decrease) increase in deferred revenue	(16,140)	37,107
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	25,534	(14,139)
Total adjustments	(163,523)	(14,778)
Net cash (used in) provided by operating activities	(87,502)	53,527
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(95,775)	(253,878)
Sales or maturities of marketable securities	80,456	82,469
Capital expenditures	(114,162)	(64,822)
Net cash used in investing activities	(129,481)	(236,231)
<b>Cash flows from financing activities:</b>		
Proceeds (payments) in connection with facility and capital lease obligations	6,738	(262)
Repayments of convertible senior notes	(16,686)	—
Payments in connection with reduction of outstanding warrants	(124,531)	—
Proceeds from issuance of Common Stock	76,273	55,042
Payments in connection with Common Stock tendered for employee tax obligations	(21,192)	(63,086)
Excess tax benefit from stock-based compensation	155,569	117,260
Net cash provided by financing activities	76,171	108,954
Net decrease in cash and cash equivalents	(140,812)	(73,750)
Cash and cash equivalents at beginning of period	648,719	535,608
Cash and cash equivalents at end of period	\$ 507,907	\$ 461,858

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

**REGENERON PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)***(Unless otherwise noted, dollars in thousands, except per share data)***1. Interim Financial Statements**

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2014 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

In addition, the previously issued (i) Consolidated Balance Sheet as of December 31, 2014 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and (ii) Condensed Consolidated Statement of Operations and Comprehensive Income for the three months ended March 31, 2014 and Condensed Consolidated Statement of Cash Flows for the three months ended March 31, 2014 contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, have each been revised in this Quarterly Report on Form 10-Q to reflect a correction in the Company's accounting for certain stock option awards. See Note 4.

**2. Product Sales**

EYLEA<sup>®</sup> net product sales in the United States totaled \$541.1 million and \$359.0 million for the three months ended March 31, 2015 and 2014, respectively. In addition, ARCALYST<sup>®</sup> net product sales totaled \$3.5 million and \$3.4 million for the three months ended March 31, 2015 and 2014, respectively.

For the three months ended March 31, 2015 and 2014, the Company recorded 69% and 79%, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the three months ended March 31, 2015 and 2014.

	<b>Rebates &amp; Chargebacks</b>	<b>Distribution- Related Fees</b>	<b>Other Sales- Related Deductions</b>	<b>Total</b>
Balance as of December 31, 2014	\$ 3,083	\$ 21,166	\$ 532	\$ 24,781
Provision related to current period sales	11,353	24,781	1,383	37,517
Credits/payments	(9,779)	(13,036)	(1,411)	(24,226)
Balance as of March 31, 2015	<u>\$ 4,657</u>	<u>\$ 32,911</u>	<u>\$ 504</u>	<u>\$ 38,072</u>
Balance as of December 31, 2013	\$ 4,400	\$ 19,663	\$ 538	\$ 24,601
Provision related to current period sales	6,886	16,858	448	24,192
Credits/payments	(6,664)	(16,310)	(454)	(23,428)
Balance as of March 31, 2014	<u>\$ 4,622</u>	<u>\$ 20,211</u>	<u>\$ 532</u>	<u>\$ 25,365</u>

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**
*(Unless otherwise noted, dollars in thousands, except per share data)*
**3. Collaboration Agreements**
**a. Sanofi**

Sanofi collaboration revenue, as detailed below, consisted primarily of (i) recognition of previously deferred revenue related to the companies' ZALTRAP® collaboration agreement, and (ii) reimbursement for research and development expenses that the Company incurred, partly offset by sharing of pre-launch commercialization expenses, in connection with the companies' antibody collaboration.

<b>Sanofi Collaboration Revenue</b>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>ZALTRAP:</b>		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	\$ (3,212)
Reimbursement of Regeneron research and development expenses	\$ 686	1,092
Other	15,236	2,177
<b>Total ZALTRAP</b>	<b>15,922</b>	<b>57</b>
<b>Antibody:</b>		
Reimbursement of Regeneron research and development expenses	168,820	126,822
Reimbursement of Regeneron commercialization-related expenses	8,458	—
Regeneron's share of losses in connection with commercialization of antibodies	(22,405)	—
Other	2,561	3,629
<b>Total Antibody</b>	<b>157,434</b>	<b>130,451</b>
	<b>\$ 173,356</b>	<b>\$ 130,508</b>

**ZALTRAP**

In September 2003, the Company entered into a collaboration agreement ("ZALTRAP Collaboration Agreement") with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.) to jointly develop and commercialize ZALTRAP. Under the terms of the ZALTRAP Collaboration Agreement, as amended, Regeneron and Sanofi shared co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan, and the Company was entitled to receive a percentage of sales of ZALTRAP in Japan. Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), for patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013.

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), with an effective date of July 1, 2014. Under the terms of the Amended ZALTRAP Agreement, Sanofi will be solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay the Company a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. The Company will also be paid for all quantities of ZALTRAP manufactured by it, pursuant to a supply agreement, through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities, or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement. Unless terminated earlier in accordance with

**REGENERON PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

*(Unless otherwise noted, dollars in thousands, except per share data)*

its provisions, the Amended ZALTRAP Agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing ZALTRAP.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015 the Company recognized \$14.9 million of previously deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since the risk of inventory loss no longer exists, and (ii) the unamortized portion of up-front payments from Sanofi as the Company has no further performance obligations. In addition, in the first quarter of 2015, the Company recorded \$19.8 million in technology licensing and other revenue, primarily related to (i) revenues earned from Sanofi based on a percentage of net sales of ZALTRAP and (ii) revenues earned from Sanofi for manufacturing ZALTRAP commercial supplies.

*Antibodies*

Under the Company's antibody collaboration agreement with Sanofi, agreed upon worldwide research and development expenses incurred by both companies during the term of the agreement are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended March 31, 2015 and 2014, the Company recognized as additional research and development expense \$25.0 million and \$23.8 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent<sup>®</sup> and sarilumab.

Effective in the second and fourth quarters of 2014, the Company and Sanofi began sharing pre-launch commercialization expenses related to Praluent and sarilumab, respectively, in accordance with the companies' antibody collaboration agreement.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors and ligands in ophthalmology. With respect to PDGF antibodies, the Company made two \$5.0 million development milestone payments to Sanofi in the first quarter of 2014, which were recorded as research and development expense. The Company is also obligated to pay up to \$30.0 million in additional potential development milestones as well as royalties on any future sales of PDGF antibodies.

***b. Bayer HealthCare LLC***

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. In addition, in January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta).

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

The collaboration revenue the Company earned from Bayer HealthCare is detailed below:

<b>Bayer HealthCare Collaboration Revenue</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>EYLEA:</b>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 89,426	\$ 61,159
Sales milestones	15,000	30,000
Cost-sharing of Regeneron EYLEA development expenses	2,657	20,347
Other	12,912	10,932
Total EYLEA	119,995	122,438
<b>PDGFR-beta antibody:</b>		
Cost-sharing of REGN2176-3 development expenses	1,254	513
Other	2,597	2,361
Total PDGFR-beta	3,851	2,874
<b>Total Bayer HealthCare collaboration revenue</b>	<b>\$ 123,846</b>	<b>\$ 125,312</b>

*EYLEA outside the United States*

In the first quarter of 2015, the Company earned a \$15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding \$200 million over a twelve-month period. In the first quarter of 2014, the Company earned two \$15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding \$500 million and \$600 million, respectively, over a twelve-month period.

In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following branch retinal vein occlusion ("BRVO"). In connection with this decision, Bayer HealthCare reimbursed Regeneron \$15.7 million for a defined share of the EYLEA global development costs that the Company had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014 and is included with "Cost-sharing of Regeneron EYLEA development expenses" in the table above. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). The Company is entitled to receive a tiered percentage of EYLEA net sales in Japan.

*PDGFR-beta antibody outside the United States*

In January 2014, the Company entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer HealthCare made a \$25.5 million non-refundable upfront payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. The \$25.5 million upfront payment was initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. Bayer HealthCare is also obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made two \$2.5 million development milestone payments to the Company in the first quarter of 2014 (both of which, for the purpose of revenue recognition, were not considered substantive).

**REGENERON PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

*(Unless otherwise noted, dollars in thousands, except per share data)*

**4. Stock-based Compensation**

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's 2014 Long-Term Incentive Plan based on the grant-date fair value of those awards. The Company recognized stock-based compensation expense of \$103.8 million and \$75.8 million in the first quarter of 2015 and 2014, respectively.

*Revisions of Previously-Issued Financial Statements*

During the first quarter of 2015, the Company determined that for certain stock option awards granted to an employee in prior periods, the incorrect requisite service period was utilized in determining the period over which the related compensation expense should have been recorded. Such awards were made as part of the Company's annual employee option grants in December of each applicable year. As a result, compensation expense for the three months and years ended December 31, 2014 and 2013 was understated, and compensation expense for the three months ended March 31, 2014 and 2013, June 30, 2014 and 2013, and September 30, 2014 and 2013 was overstated. These revisions consisted entirely of non-cash adjustments, and therefore had no impact on the Company's previously reported total cash flows from operating activities and total cash flows in its Statements of Cash Flows. The Company evaluated the impact of these items on prior periods, assessing materiality quantitatively and qualitatively, and concluded that the errors were not considered to be material to any previously-issued quarterly or annual financial statements. However, the Company concluded that it would revise the applicable prior period amounts in this filing to reflect the impact of these corrections because the cumulative amount of such corrections is expected to be material to the year ending December 31, 2015. The Company's prior-period financial statements will reflect these revisions for the applicable periods presented in future filings.

The table below presents the impact of these revisions, including the related tax effect, on the Company's previously-filed financial statements.

**REGENERON PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**  
*(Unless otherwise noted, dollars in thousands, except per share data)*

	<b>December 31, 2014</b>		
	<b>As Previously Reported</b>	<b>Adjustments</b>	<b>As Revised</b>
<b>Balance Sheet Data:</b>			
Deferred tax assets (noncurrent)	\$ 266,869	\$ 22,152	\$ 289,021
Total assets	3,871,827	22,152	3,893,979
Additional paid-in capital	2,404,118	60,890	2,465,008
Retained earnings	255,382	(38,738)	216,644
Total stockholders' equity	2,542,325	22,152	2,564,477
Total liabilities and stockholders' equity	3,871,827	22,152	3,893,979

	<b>Three Months Ended March 31, 2014</b>		
	<b>As Previously Reported</b>	<b>Adjustments</b>	<b>As Revised</b>
<b>Consolidated Statement of Operations Data:</b>			
Selling, general, and administrative	\$ 108,850	\$ (5,623)	\$ 103,227
Total operating expenses	439,801	(5,623)	434,178
Income from operations	185,939	5,623	191,562
Income before income taxes	175,263	5,623	180,886
Income tax expense	109,820	2,761	112,581
Net income	65,443	2,862	68,305
Net income per share - basic	\$ 0.66	\$ 0.03	\$ 0.69
Net income per share - diluted	\$ 0.58	\$ 0.03	\$ 0.61

**Consolidated Statement of Cash Flows Data:**

*Cash flows from operating activities*

Net income	\$ 65,443	\$ 2,862	\$ 68,305
Non-cash compensation expense	81,408	(5,623)	75,785
Deferred taxes	(8,522)	2,761	(5,761)

**REGENERON PHARMACEUTICALS, INC.**
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The tables below present the impact of these revisions, including the related tax effects, on additional previously-filed interim and year-end Consolidated Statements of Operations (i) for the three and six months ended June 30, 2014, (ii) for the three and nine months ended September 30, 2014, and (iii) for the three months and year ended December 31, 2014.

	Three Months Ended June 30, 2014			Six Months Ended June 30, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	\$ 102,414	\$ (5,684)	\$ 96,730	\$ 211,264	\$ (11,307)	\$ 199,957
Total operating expenses	443,294	(5,684)	437,610	883,095	(11,307)	871,788
Income from operations	222,406	5,684	228,090	408,345	11,307	419,652
Income before income taxes	203,119	5,684	208,803	378,382	11,307	389,689
Income tax expense	110,384	2,068	112,452	220,204	4,829	225,033
Net income	92,735	3,616	96,351	158,178	6,478	164,656
Net income per share - basic	\$ 0.92	\$ 0.04	\$ 0.96	\$ 1.58	\$ 0.07	\$ 1.65
Net income per share - diluted	\$ 0.82	\$ 0.03	\$ 0.85	\$ 1.40	\$ 0.06	\$ 1.46

	Three Months Ended September 30, 2014			Nine Months Ended September 30, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	\$ 149,748	\$ (5,745)	\$ 144,003	\$ 361,012	\$ (17,052)	\$ 343,960
Total operating expenses	543,069	(5,745)	537,324	1,426,164	(17,052)	1,409,112
Income from operations	182,719	5,745	188,464	591,064	17,052	608,116
Income before income taxes	176,078	5,745	181,823	554,460	17,052	571,512
Income tax expense	96,358	2,090	98,448	316,562	6,919	323,481
Net income	79,720	3,655	83,375	237,898	10,133	248,031
Net income per share - basic	\$ 0.79	\$ 0.04	\$ 0.83	\$ 2.37	\$ 0.10	\$ 2.47
Net income per share - diluted	\$ 0.70	\$ 0.03	\$ 0.73	\$ 2.10	\$ 0.09	\$ 2.19

	Three Months Ended December 31, 2014			Year Ended December 31, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	\$ 143,743	\$ 31,564	\$ 175,307	\$ 504,755	\$ 14,512	\$ 519,267
Total operating expenses	554,962	31,564	586,526	1,981,126	14,512	1,995,638
Income from operations	247,367	(31,564)	215,803	838,431	(14,512)	823,919
Income before income taxes	221,287	(31,564)	189,723	775,747	(14,512)	761,235
Income tax expense	111,111	(11,483)	99,628	427,673	(4,564)	423,109
Net income	110,176	(20,081)	90,095	348,074	(9,948)	338,126
Net income per share - basic	\$ 1.09	\$ (0.20)	\$ 0.89	\$ 3.46	\$ (0.10)	\$ 3.36
Net income per share - diluted	\$ 0.96	\$ (0.18)	\$ 0.78	\$ 3.07	\$ (0.09)	\$ 2.98

**REGENERON PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)***(Unless otherwise noted, dollars in thousands, except per share data)***5. Net Income Per Share**

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net income - basic and diluted	\$ 76,021	\$ 68,305
<i>(Shares in thousands)</i>		
Weighted average shares - basic	102,227	98,709
Effect of dilutive securities:		
Stock options	9,313	9,879
Restricted stock	467	401
Warrants	2,512	3,162
Dilutive potential shares	12,292	13,442
Weighted average shares - diluted	114,519	112,151
Net income per share - basic	\$ 0.74	\$ 0.69
Net income per share - diluted	\$ 0.66	\$ 0.61

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

<i>(Shares in thousands)</i>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Stock options	3,673	3,646
Convertible senior notes	1,929	4,761

**REGENERON PHARMACEUTICALS, INC.**
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**6. Marketable Securities**

Marketable securities as of March 31, 2015 and December 31, 2014 consist of both debt securities issued by investment grade institutions as well as equity securities. The Company also held restricted marketable securities as of December 31, 2014, consisting of the Company's investment in Avalanche Biotechnologies, Inc. common shares, which were subject to customary transfer restrictions until January 2015 under a lock-up agreement with the underwriters of Avalanche's initial public offering.

The following tables summarize the Company's investments in marketable securities:

<b>As of March 31, 2015</b>	<b>Amortized Cost Basis</b>	<b>Unrealized</b>		<b>Fair Value</b>
		<b>Gains</b>	<b>Losses</b>	
<i>Unrestricted</i>				
Corporate bonds	\$ 530,693	\$ 898	\$ (99)	\$ 531,492
U.S. government and government agency obligations	56,433	201	—	56,634
Municipal bonds	39,807	52	(3)	39,856
Equity securities	17,005	72,575	—	89,580
	<u>\$ 643,938</u>	<u>\$ 73,726</u>	<u>\$ (102)</u>	<u>\$ 717,562</u>
<b>As of December 31, 2014</b>				
<i>Unrestricted</i>				
Corporate bonds	\$ 548,832	\$ 136	\$ (1,462)	\$ 547,506
U.S. government and government agency obligations	28,596	3	(46)	28,553
Municipal bonds	37,044	37	(43)	37,038
Equity securities	2,005	5,374	—	7,379
	<u>616,477</u>	<u>5,550</u>	<u>(1,551)</u>	<u>620,476</u>
<i>Restricted</i>				
Equity securities	15,000	76,439	—	91,439
	<u>\$ 631,477</u>	<u>\$ 81,989</u>	<u>\$ (1,551)</u>	<u>\$ 711,915</u>

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of March 31, 2015 mature at various dates through August 2024. The fair values of debt security investments by contractual maturity consist of the following:

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Maturities within one year	\$ 234,257	\$ 251,761
Maturities after one year through five years	392,624	360,208
Maturities after five years through ten years	1,101	1,128
	<u>\$ 627,982</u>	<u>\$ 613,097</u>

**REGENERON PHARMACEUTICALS, INC.**  
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The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
<b>As of March 31, 2015</b>						
Corporate bonds	\$ 136,720	\$ (85)	\$ 4,139	\$ (14)	\$ 140,859	\$ (99)
Municipal bonds	3,938	(3)	—	—	3,938	(3)
	<u>\$ 140,658</u>	<u>\$ (88)</u>	<u>\$ 4,139</u>	<u>\$ (14)</u>	<u>\$ 144,797</u>	<u>\$ (102)</u>
<b>As of December 31, 2014</b>						
Corporate bonds	\$ 390,613	\$ (1,462)	—	—	\$ 390,613	\$ (1,462)
U.S. government and government agency obligations	25,549	(46)	—	—	25,549	(46)
Municipal bonds	10,779	(43)	—	—	10,779	(43)
	<u>\$ 426,941</u>	<u>\$ (1,551)</u>	<u>—</u>	<u>—</u>	<u>\$ 426,941</u>	<u>\$ (1,551)</u>

For the three months ended March 31, 2015 and 2014, total realized gains and losses on sales of marketable securities were not material.

Changes in the Company's accumulated other comprehensive income (loss) for the three months ended March 31, 2015 and 2014 related to unrealized gains and losses on available-for-sale marketable securities. For the three months ended March 31, 2015 and 2014, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to realized gains and losses on sales of marketable securities.

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**7. Fair Value Measurements**

The Company's assets that are measured at fair value on a recurring basis consist of the following:

	Fair Value	Fair Value Measurements at Reporting Date Using	
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
<b>As of March 31, 2015</b>			
Available-for-sale marketable securities:			
<i>Unrestricted</i>			
Corporate bonds	\$ 531,492	—	\$ 531,492
U.S. government and government agency obligations	56,634	—	56,634
Municipal bonds	39,856	—	39,856
Equity securities	89,580	\$ 89,580	—
	<u>\$ 717,562</u>	<u>\$ 89,580</u>	<u>\$ 627,982</u>
<b>As of December 31, 2014</b>			
Available-for-sale marketable securities:			
<i>Unrestricted</i>			
Corporate bonds	\$ 547,506	—	\$ 547,506
U.S. government and government agency obligations	28,553	—	28,553
Municipal bonds	37,038	—	37,038
Equity securities	7,379	\$ 7,379	—
	<u>620,476</u>	<u>7,379</u>	<u>613,097</u>
<i>Restricted</i>			
Equity securities	91,439	—	91,439
	<u>\$ 711,915</u>	<u>\$ 7,379</u>	<u>\$ 704,536</u>

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three months ended March 31, 2015 and 2014.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2015 and 2014.

During the three months ended March 31, 2015, transfers of marketable securities from Level 2 to Level 1 were \$91.4 million in connection with the lapse of the transfer restrictions on the Company's investment in Avalanche common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2015, and there were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2014.

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As of March 31, 2015 and December 31, 2014, the Company had \$162.7 million and \$169.4 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") that will mature on October 1, 2016 unless earlier converted or repurchased. As described in Note 10, a portion of the Notes was surrendered for conversion during the first quarter of 2015. The fair value of the outstanding Notes was estimated to be \$876.0 million and \$819.8 million as of March 31, 2015 and December 31, 2014, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

Additionally, as described in Note 10, pursuant to a November 2014 amendment agreement with a warrant holder, a portion of the Company's warrants were classified as a liability and measured at fair value as of December 31, 2014. The fair value of this liability was estimated to be \$87.5 million as of December 31, 2014, and was determined based on Level 2 inputs, such as market and observable sources. During the first quarter of 2015, upon expiration of the November 2014 amendment agreement, the remaining warrants were re-measured at fair value and reclassified back to additional paid-in capital.

## 8. Inventories

Inventories consist of the following:

	March 31, 2015	December 31, 2014
Raw materials	\$ 9,644	\$ 10,923
Work-in-process	83,990	73,519
Finished goods	11,398	10,768
Deferred costs	28,831	33,651
	<u>\$ 133,863</u>	<u>\$ 128,861</u>

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

## 9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2015	December 31, 2014
Accounts payable	\$ 90,601	\$ 99,508
Accrued payroll and related costs	64,112	92,778
Accrued clinical trial expense	44,659	41,555
Accrued sales-related charges, deductions, and royalties	165,511	133,085
Other accrued expenses and liabilities	97,879	116,563
	<u>\$ 462,762</u>	<u>\$ 483,489</u>

## 10. Debt

### a. Convertible Debt

In the first quarter of 2015, the Company settled conversion obligations for \$16.7 million principal amount of the Company's original \$400.0 million aggregate principal amount of Notes that was previously surrendered for conversion. In accordance with the terms of the Notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in the first quarter of 2015, the Company (i) paid \$16.7 million in cash, (ii) issued 146,253 shares

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of Common Stock, and (iii) allocated \$62.6 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity. In addition, the Company recognized a \$0.9 million loss on the debt extinguishment in connection with the Notes that were surrendered for conversion during the first quarter of 2015.

In connection with the initial offering of the Notes in October 2011, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, which were recorded to additional paid-in capital. As a result of the Note conversions described above, in the first quarter of 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 146,248 shares of Common Stock, which was approximately equal to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or \$12.3 million, as Treasury Stock during the first quarter of 2015.

In addition to the Note conversions described above, the Company received notification in April 2015 that an additional \$127.3 million principal amount of the Notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2015. The Company has elected to settle the related conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company expects to receive shares of Common Stock equivalent to the number of shares the Company will be required to issue to settle the non-cash portion of the related Note conversions.

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 493,229. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding \$397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under the amendment agreement in February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the 493,229 warrants from additional paid-in capital to a liability in November 2014, with such liability subsequently measured at fair value with changes in fair value recognized in earnings. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, the Company recorded a \$59.8 million accrued liability as of December 31, 2014 in connection with the warrant holder reducing the number of warrants it held. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, in February 2015 the Company paid a total of \$124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, the remaining warrants were re-measured at fair value, and \$23.3 million was reclassified back to additional paid-in capital, consistent with the original classification of the warrants under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

Additionally, in February 2015, the Company entered into another amendment agreement with the same warrant holder whereby the parties agreed to further reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 76,749, for an aggregate amount payable by the Company not to exceed \$24.0 million. The reduction in the number of warrants will be determined based on the number of warrants with respect to which the warrant holder has closed out its hedge position, provided that the warrant holder does not effect any purchases at a price per share exceeding \$408.00 per share, during the period starting on March 2, 2015 and ending no later than May 7, 2015. The Company may settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock within three days following the warrant holder closing out its hedge position. Therefore, any payments made under the amendment agreement will be recorded to additional paid-in capital, consistent with the original accounting for the warrants under the 2011 issuance. During the first quarter of 2015, the reduction in the number of warrants in accordance with the February 2015 amended agreement was not material.

**b. Credit Facility**

In March 2015, the Company entered into an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a \$750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to \$250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a \$100.0 million sublimit for letters of credit. The Credit Agreement includes an option for the

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Company to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

Any loans under the Credit Facility have a variable interest rate based on either the London Interbank Offered Rate ("LIBOR") or an alternate base rate, plus an applicable margin that varies with the Company's debt rating and total leverage ratio. The Company had no borrowings outstanding under the Credit Facility as of March 31, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. The Company was in compliance with all covenants of the Credit Facility as of March 31, 2015.

**11. Income Taxes**

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of \$200.5 million and \$112.6 million for the three months ended March 31, 2015 and 2014, respectively. The Company's effective tax rate was 72.5% and 62.2% for the three months ended March 31, 2015 and 2014, respectively. The Company's effective tax rate for the three months ended March 31, 2015 was negatively impacted by (i) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, (ii) the non-deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities.

The Company's effective tax rate for the three months ended March 31, 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) New York state tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York state income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the Company reducing its related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in the Company's effective tax rate by 10.4% for the first quarter of 2014.

The Company also recorded an income tax benefit in its Statement of Comprehensive Income of \$2.5 million for the three months ended March 31, 2015, in connection with unrealized gains (losses) on available-for-sale marketable securities. For the three months ended March 31, 2014, no such income tax provision or benefit was required.

**12. Statement of Cash Flows**

*Supplemental disclosure of non-cash investing and financing activities*

Included in accounts payable and accrued expenses as of March 31, 2015 and December 31, 2014 were \$84.1 million and \$56.2 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of March 31, 2014 and December 31, 2013 were \$17.6 million and \$16.1 million, respectively, of accrued capital expenditures

Included in accounts payable and accrued expenses as of December 31, 2014 was \$7.5 million for the Company's conversion settlement obligation related to the Company's convertible senior notes. No such amounts were payable as of March 31, 2014 and December 31, 2013, and the amount of such conversion settlement obligation was not material as of March 31, 2015.

Included in accounts payable and accrued expenses as of December 31, 2014 was \$59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position. Additionally, included within other current liabilities as of December 31, 2014 was \$87.5 million in connection with the estimated fair value of the remaining warrant liability. See Note 10. There were no such liabilities recorded in connection with warrants as of March 31, 2015, March 31, 2014, and December 31, 2013.

The Company recognized a facility lease obligation of \$10.8 million and \$19.4 million during the three months ended March 31, 2015 and 2014, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

*(Unless otherwise noted, dollars in thousands, except per share data)*

*Subsequent event*

In April 2015, the Company acquired an approximate 100-acre parcel of undeveloped land adjacent to its current Tarrytown, New York location for an aggregate purchase price of \$73.0 million. The Company intends to develop this property to accommodate and support its growth, primarily in connection with expanding its existing research and development and office space.

**13. Legal Matters**

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

*Proceedings Relating to '287 Patent and '018 Patent*

The Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 (the "'287 Patent") and its U.S. Patent No. 8,502,018 (the "'018 Patent"), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (the "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), the Company claims infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '018 Patent (as applicable). At this time the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

*Proceedings Relating to PCSK9 Antibody (Praluent)*

On October 17, 2014 and October 28, 2014, Amgen Inc. filed complaints against Regeneron, Sanofi, Aventisub LLC (subsequently removed and replaced with Sanofi-Aventis U.S. LLC), and Aventis Pharmaceuticals, Inc. in the United States District Court for the District of Delaware seeking an injunction to prohibit Regeneron and the other defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) Praluent, the antibody to PCSK9 for LDL cholesterol reduction Regeneron is jointly developing with Sanofi. On November 11, 2014 and November 17, 2014 Amgen filed complaints against Regeneron, Sanofi, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. in the same court seeking the same relief. Amgen asserts U.S. Patent Nos. 8,563,698, 8,829,165, and 8,859,741 in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 in the second complaint, U.S. Patent No. 8,883,983 in the third complaint, and U.S. Patent No. 8,889,834 in the fourth complaint. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. On December 15, 2014, all of the four proceedings were consolidated into a single case. This matter has not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to estimate a range of possible loss, if any.

**14. Recently Issued Accounting Standards**

In May 2014, the FASB issued a new standard related to revenue recognition, *Revenue from Contracts with Customers*, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. The new standard will be effective for annual and interim reporting periods beginning after December 15, 2016, and early adoption is not permitted. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. The Company has not yet determined its method of transition and is evaluating the impact that this guidance will have on the Company's financial statements.

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

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation Regeneron's human genetics initiative; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation Praluent<sup>®</sup> (alirocumab), sarilumab, and dupilumab; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA<sup>®</sup>), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures and income tax obligations, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

### Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We commercialize medicines for eye diseases and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis (RA), asthma, and atopic dermatitis.

Our total revenues were \$869.6 million in the first quarter of 2015, compared to \$625.7 million in the first quarter 2014. Our net income was \$76.0 million, or \$0.66 per diluted share, in the first quarter of 2015, compared to net income of \$68.3 million, or \$0.61 per diluted share, in the first quarter of 2014. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have two marketed products:

- **EYLEA (afibercept) Injection**, known in the scientific literature as VEGF Trap-Eye, which is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), macular edema following central retinal vein occlusion (CRVO), and diabetic macular edema (DME). In addition, (i) in October 2014 and February 2015, the U.S. Food and Drug Administration (FDA) and European Commission, respectively, approved EYLEA for the treatment of macular edema following retinal vein occlusion (RVO), which includes macular edema following branch retinal vein occlusion (BRVO), (ii) in September 2014, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved EYLEA for myopic choroidal neovascularization (mCNV), and (iii) in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.

- **ARCALYST® (rilonacept) Injection for Subcutaneous Use**, which is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 years and older.

In February 2015, we and Sanofi entered into an amended and restated ZALTRAP® agreement (Amended ZALTRAP Agreement). Under the terms of the Amended ZALTRAP Agreement, Sanofi will be solely responsible for the development and commercialization of ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. Refer to "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP" below for further details of the Amended ZALTRAP Agreement. ZALTRAP is currently available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

We have 16 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 15 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our *VelocImmune*® technology.

## Trap-based Clinical Programs

### **EYLEA**

In Phase 3 clinical development for the treatment of wet AMD (Asia) and DME (Asia) in collaboration with Bayer HealthCare. As described below, EYLEA is also being studied in combination with (i) an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) an antibody to angiopoietin-2 (Ang2).

### Antibody-based Clinical Programs in Collaboration with Sanofi

#### **Praluent (alirocumab)**

Antibody to PCSK9. In Phase 3 clinical development for low-density lipoprotein (LDL) cholesterol reduction and for the prevention of cardiovascular events.

#### **Sarilumab (REGN88)**

Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).

#### **Dupilumab (REGN668)**

Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in children (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

#### **REGN1033**

Antibody to myostatin (GDF8). In Phase 2 clinical development in skeletal muscle disorders.

#### **REGN2222**

Antibody against respiratory syncytial virus (RSV). In Phase 1 clinical development. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

### Antibody-based Clinical Programs in Collaboration with Bayer HealthCare

#### **REGN2176-3**

Combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 2 clinical study for the treatment of wet AMD initiated in the second quarter of 2015.

### Antibody-based Clinical Programs Developing Independently

#### **REGN1908-1909\***

Antibody combination in Phase 1/Phase 2 clinical development against allergic disease.

#### **REGN1500\***

Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Studies are ongoing under a partial clinical hold by the FDA that excludes women of childbearing potential.

#### **REGN1400**

Antibody to ErbB3. In Phase 1 clinical development in oncology.

#### **REGN1154\***

Antibody against an undisclosed target. Phase 1 clinical study in Australia completed.

#### **REGN1193\***

Antibody in Phase 1 clinical development against an undisclosed target.

#### **REGN1979**

Bispecific antibody against CD20 and CD3. In Phase 1 clinical development in oncology.

#### **REGN910-3\*\***

Combination product comprised of an antibody to Ang2 co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. In Phase 1 clinical development for the treatment of wet AMD and DME.

#### **REGN2810\***

Antibody to PD-1. Phase 1 clinical study in oncology initiated in the first quarter of 2015.

#### **Fasinumab (REGN475)\***

Antibody to Nerve Growth Factor (NGF). In development for the treatment of pain; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

\* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of the product candidate.

\*\* We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone and royalties on any future sales of the product candidate.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to combine that foundation with our clinical development, manufacturing, and commercial capabilities. We are executing our long-term objective to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*<sup>®</sup> technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*<sup>®</sup> technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*) and cell line expression technologies (*VelociMab*<sup>®</sup>) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC performs sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC leverages laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

## Marketed Products

### *EYLEA (afibercept) Injection*

We commenced sales of EYLEA in the United States for the treatment of wet AMD in November 2011, macular edema following CRVO in September 2012, DME in July 2014, and macular edema following RVO in October 2014. In addition, in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Outside the United States, Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012, macular edema secondary to CRVO in the fourth quarter of 2013, visual impairment due to DME in the third quarter of 2014, and mCNV in Japan in the fourth quarter of 2014. In February 2015, the European Commission approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In the fourth quarter of 2014, Bayer HealthCare submitted a regulatory application in China for EYLEA for the treatment of wet AMD. In addition, Bayer HealthCare has submitted an application to the MHLW seeking marketing authorization in Japan for EYLEA for the treatment of macular edema following BRVO. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries.

We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets, and records revenue from sales of EYLEA outside the United States, where, for countries other than Japan, the companies share equally the profits and losses from sales of EYLEA. In Japan, we are entitled to receive a percentage of the sales of EYLEA. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from such sales.

Net product sales of EYLEA in the United States were \$541.1 million in the first quarter of 2015, compared to \$359.0 million in the first quarter of 2014. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were \$291.8 million in the first quarter of 2015, compared to \$218.1 million in the first quarter of 2014.

### *ARCALYST (rilonacept) Injection for Subcutaneous Use*

ARCALYST is available in the United States for the treatment of CAPS in adults and children 12 years and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. Net product sales of ARCALYST were \$3.5 million in the first quarter of 2015, compared to \$3.4 million in the first quarter of 2014.

## Trap-based Clinical Programs

### *EYLEA - Ophthalmologic Diseases*

#### Overview

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet AMD, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. CRVO is caused by obstruction of the central retinal vein that leads to a back-up of blood and fluid in the retina. Release of VEGF contributes to increased vascular permeability in the eye and macular edema. In BRVO, a blockage occurs in the blood vessels branching from the main vein draining the retina, resulting in the release of VEGF and consequent retinal edema. For centrally involved DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision. Wet AMD, diabetic retinopathy (which includes DME), and RVO are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by neovascular proliferation and/or retinal edema.

EYLEA is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

#### DME

*Phase 3 VISTA-DME and VIVID-DME Trials.* We conducted the VISTA-DME study in the United States, and Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation. The VIVID-DME trial will continue as planned up to 148 weeks.

In March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME.

*Phase 3 VIVID EAST-DME Study.* In February 2013, we and Bayer HealthCare initiated a Phase 3 study to evaluate the efficacy and safety of EYLEA in DME in Russia, China, and other Asian countries (VIVID EAST-DME). This trial is fully enrolled.

## Late-Stage Antibody-based Clinical Programs

### *Praluent for LDL cholesterol reduction*

#### Overview

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol (LDL-C) through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis that ultimately results in an increase in LDL receptors to increase the uptake of plasma LDL lipoproteins. Similar to statins, PCSK9 impacts the number of available LDL receptors and therefore plays a key role in modulating LDL-C levels in the body. PCSK9 is a secreted protein that binds to and induces the destruction of the LDL receptor, thereby interfering with cellular uptake and increasing circulating levels of LDL cholesterol. In a landmark study published in *The New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL-C, but also a significant reduction in the risk of coronary heart disease (CHD). We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called Praluent, that is intended to lower LDL cholesterol.

#### Clinical Programs

*Phase 3 ODYSSEY Program.* We and Sanofi initiated the global Phase 3 ODYSSEY program for Praluent in the second quarter of 2012. The ODYSSEY program consists of more than 23,500 patients, and includes clinical trials evaluating the effect of Praluent, dosed every two weeks, on lowering LDL cholesterol. In addition, the potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of Praluent dosed every four weeks, ODYSSEY CHOICE I and ODYSSEY CHOICE II. Patients in the ODYSSEY CHOICE I trial received Praluent 300 mg (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks. The ODYSSEY studies are being

conducted in clinical centers around the world including North America, Western and Eastern Europe, South America, Australia, and Asia.

In 2013, we and Sanofi reported data from the ODYSSEY MONO trial, which evaluated the efficacy and safety of Praluent monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. In 2014, we and Sanofi reported detailed positive results from nine additional Phase 3 ODYSSEY studies. All ten studies (ODYSSEY MONO, LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks compared to placebo or active comparator. Based on the positive results of these studies, a Biologics License Application (BLA) for U.S. regulatory approval of Praluent was submitted, and accepted by the FDA in January 2015. An FDA rare pediatric disease priority review voucher was utilized in connection with this BLA submission, as a result of which the submission was accepted by the FDA for priority review; the target date for an FDA decision on the BLA is July 24, 2015. The FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) is scheduled to meet on June 9, 2015 to discuss the BLA for Praluent. In addition, the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) for Praluent.

All patients in the ten trials received Praluent in addition to standard-of care lipid-lowering therapy, with the exception of patients in ODYSSEY MONO. The ODYSSEY ALTERNATIVE trial specifically focused on patients with a history of documented statin intolerance but allowed patients who were taking certain non-statin lipid-lowering therapies to participate in the trial. The trials included patients with LDL-C not at goal with or without a documented history of cardiovascular disease, including hypercholesterolemic patients who were at high cardiovascular (CV) risk, had an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH), and/or a history of intolerance to two or more statins, including one at the lowest dose. The trials evaluated two distinct dosing regimens: 150 mg every two weeks or 75 mg every two weeks increasing to 150 mg if needed to reach protocol-specified LDL-C targets. In the trials that used an individualized approach with 75 mg and 150 mg doses, the majority of patients reached their LDL-C goals while remaining on the 75 mg dose. The 75 mg and the 150 mg doses were delivered with a single, self-administered one-milliliter (mL) injection. A summary of primary efficacy endpoints and most common adverse events (AEs) are as follows:

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs <sup>a</sup>
		Praluent	Comparator	
<b>LONG TERM</b> <i>Praluent (n =1,553) vs. placebo (n =788)</i>  150 mg dose	All patients (high CV risk) (total n=2,341)	61% reduction	1% increase (placebo) <sup>b</sup>	Nasopharyngitis, upper respiratory tract infection, injection site reactions, influenza, diarrhea, urinary tract infection, bronchitis, myalgia, headache, back pain, arthralgia
	- HeFH subgroup (n=415)	56% reduction	7% increase (placebo) <sup>c</sup>	
	- Non-HeFH subgroup (n=1,926)	62% reduction	0.5% reduction (placebo) <sup>d</sup>	
<b>COMBO I</b> <i>Praluent (n =209) vs. placebo (n =107)</i>  75 mg/150 mg dose	High CV risk	48% reduction	2% reduction (placebo) <sup>b</sup>	Upper respiratory tract infection, nasopharyngitis, urinary tract infection, dizziness, sinusitis, injection-site reaction
<b>COMBO II</b> <i>Praluent (n =479) vs. ezetimibe (n =241)</i>  75 mg/150 mg dose	High CV risk	51% reduction	21% reduction (ezetimibe) <sup>b</sup>	Upper respiratory tract infection, accidental overdose, dizziness, myalgia
<b>OPTIONS I</b> [Baseline statin = atorvastatin 20/40 mg]  <i>Praluent (n =104) vs. ezetimibe (n =102) or double atorvastatin (n =104) or switch to rosuvastatin<sup>e</sup> (n =45)</i>  75 mg / 150 mg dose	High CV risk	44% - 54% reduction	<ul style="list-style-type: none"> <li>• 21% - 23% reduction (ezetimibe)<sup>f</sup></li> <li>• 5% reduction (double statin dose)<sup>b</sup></li> <li>• 21% reduction (statin switch)<sup>b</sup></li> </ul>	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain

(continued)

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs <sup>a</sup>
		Praluent	Comparator	
<b>OPTIONS II</b> [Baseline statin = rosuvastatin 10/20 mg]  Praluent (n =103) vs. ezetimibe (n =101) or double rosuvastatin (n =101)  75 mg / 150 mg dose	High CV risk	36% - 51% reduction	<ul style="list-style-type: none"> <li>• 11% -14% reduction (ezetimibe)<sup>g</sup></li> <li>• 16% reduction (statin switch)<sup>g</sup></li> </ul>	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain
<b>ALTERNATIVE</b> Praluent (n =126) vs. ezetimibe (n =125)  [Validation arm = atorvastatin 20 mg (n =63)]  75 mg / 150 mg dose	High CV risk and history of intolerance to two or more statins	45% reduction	15% reduction (ezetimibe) <sup>b</sup>	Myalgia, nasopharyngitis, arthralgia, upper respiratory tract infection, headache, fatigue
<b>HIGH FH</b> Praluent (n =72) vs. placebo (n =35)  150 mg dose	HeFH	46% reduction	7% reduction (placebo) <sup>b</sup>	Nasopharyngitis, injection-site reaction, diarrhea, sinusitis, bronchitis, headache, fatigue
<b>FH I</b> Praluent (n =323) vs. placebo (n =163)  75 mg / 150 mg dose	HeFH	49% reduction	9% increase (placebo) <sup>b</sup>	Injection site reactions, nasopharyngitis, influenza, headache
<b>FH II</b> Praluent (n =167) vs. placebo (n =82)  75 mg / 150 mg dose	HeFH	49% reduction	3% increase (placebo) <sup>b</sup>	
<b>MONO</b> Praluent (n =52) vs. ezetimibe (n =51)  75 mg/150 mg dose	Moderate CV risk	48% reduction	16% reduction (ezetimibe) <sup>b</sup>	Nasopharyngitis, influenza, upper respiratory tract infection

- a. Occurred in at least 5% of Praluent-treated patients. Rare allergic reactions have also been reported.
- b. p<0.0001
- c. 95% confidence interval of the least squares (LS) mean difference vs. placebo: 57.5% - 69% reduction
- d. 95% confidence interval of the LS mean difference vs. placebo: 59% - 64% reduction
- e. 45 patients on atorvastatin 40 mg starting dose switched to rosuvastatin 40 mg
- f. For patients on atorvastatin 20 mg starting dose p=0.0004; for patients on atorvastatin 40 mg starting dose p<0.0001
- g. For patients on rosuvastatin 10 mg starting dose p<0.0001; patients on rosuvastatin 20 mg starting dose did not reach statistical significance

The ODYSSEY ALTERNATIVE trial reassessed statin intolerance, as measured by skeletal muscle AEs, by including a validation arm (atorvastatin 20 mg). Although the trial was not designed to demonstrate differences in AEs between treatment groups, in this trial, there were fewer skeletal muscle AEs in the Praluent group compared to patients treated with atorvastatin (32.5% versus 46%, hazard ratio = 0.61; nominal p value = 0.042), and fewer compared to ezetimibe (41%). In addition, there were numerically fewer discontinuations for skeletal muscle AEs in the Praluent group (Praluent 16%, ezetimibe 20%, atorvastatin 22%). In comparison, the overall rate of discontinuations for skeletal muscle AEs across the Phase 2 and 3 Praluent placebo-controlled studies, where the majority of patients were also on statins, was 0.4% for Praluent (n =2,476) and 0.5% for placebo (n = 1,276).

In January 2015, we and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with Praluent versus placebo in patients with hypercholesterolemia. In these trials dosing every four weeks, the mean percent reduction in LDL-C from baseline was

consistent with that seen in previous Phase 3 trials evaluating Praluent in every other week dosing. The most common AEs in the trials (occurring in at least 5% of Praluent-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the Praluent groups compared to placebo. Detailed data were presented at the American College of Cardiology (ACC) conference in March 2015.

In March 2015, 18-month (78-week) results of the ODYSSEY LONG TERM Phase 3 trial of Praluent were published online in *The New England Journal of Medicine*. In the ODYSSEY LONG TERM trial, Praluent 150 mg every two weeks reduced LDL-C by an additional 62% at week 24 when compared to placebo, with consistent LDL-C lowering maintained over 78 weeks. Patients received 78 weeks of treatment followed by an eight-week safety assessment. Patients self-administered a subcutaneous injection every two weeks via a pre-filled syringe. Key results included:

- Efficacy remained consistent throughout treatment, and, at week 78 there was a 56% reduction from baseline in LDL-C for Praluent versus placebo ( $p < 0.001$ ).
- At week 24, 81% of patients in the Praluent group achieved their pre-specified LDL-C goal (either 70 mg/dL or 100 mg/dL depending on baseline CV risk) compared to 8.5% for placebo ( $p < 0.001$ ).
- AEs occurred in 81% of Praluent and 83% of placebo patients, leading to discontinuation in 7.2% and 5.8% of patients, respectively. AEs were similar between groups, apart from differences in injection site reactions (5.9% Praluent, 4.2% placebo), myalgia (5.4% Praluent, 2.9% placebo), neurocognitive events (1.2% Praluent, 0.5% placebo), and ophthalmological events (2.9% Praluent, 1.9% placebo). In a 3,752-patient, pooled safety analysis of nine placebo-controlled Praluent studies, rates of skeletal muscle-related (15.1% Praluent, 15.4% placebo) and neurocognitive events (0.8% Praluent, 0.7% placebo) were generally balanced between Praluent and placebo.
- At week 78, positively adjudicated pre-specified CV AEs (including additional CV AEs beyond those in the pre-specified ODYSSEY OUTCOMES endpoint of 'major adverse cardiac events' described below) occurred in 4.6% and 5.1% of Praluent and placebo patients, respectively. CV AEs are defined as CHD death including unknown cause, non-fatal myocardial infarction (MI), fatal and non-fatal ischemic stroke, unstable angina requiring hospitalization, congestive heart failure requiring hospitalization and ischemia-driven coronary revascularization procedure.
- In a post hoc analysis using a pre-specified endpoint from the ODYSSEY OUTCOMES study that included CHD death, MI, stroke, or unstable angina requiring hospitalization, a lower rate of adjudicated major adverse cardiac events was observed in the Praluent group (27 of 1,550 patients, 1.7%) compared with the placebo group (26 of 788 patients, 3.3%; hazard ratio 0.52; 95% percent confidence interval (CI), 0.31 to 0.90; nominal  $p < 0.01$ ). The cumulative incidence curves diverged progressively over time.
- ODYSSEY LONG TERM was not designed to evaluate CV outcomes. The number of CV events seen in the post hoc analysis was relatively small, which limits the ability to draw conclusions on the effects of Praluent on CV events. The ongoing ODYSSEY OUTCOMES trial will evaluate the CV benefits of Praluent.

### ***Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases***

#### Overview

IL-6 is a key cytokine involved in the pathogenesis of RA, causing inflammation and joint destruction. Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology.

#### Rheumatoid Arthritis

**Phase 3 SARIL-RA-MOBILITY Trial.** In 2013, we and Sanofi announced that in the SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to methotrexate (MTX) therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. The 52 week SARIL-RA-MOBILITY Phase 3 trial enrolled approximately 1,200 patients with active, moderate-to-severe rheumatoid arthritis, and who were inadequate responders to MTX therapy. Patients were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week: sarilumab 200 mg, sarilumab 150 mg, or placebo. Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in all three co-primary endpoints ( $p < 0.0001$ ).

**Additional Phase 3 Studies.** We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE, SARIL-RA-MONARCH, SARIL-RA-EASY, and SARIL-RA-KAKEHASI (in Japan). In addition, the SARIL-RA-HARUKA long-term safety trial was initiated in Japan in the first quarter of 2015. SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE, and SARIL-RA-EASY are fully enrolled. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha (TNF-alpha) inhibitor therapy. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

## Non-infectious Uveitis

*Phase 2 SARIL-NIU-SATURN Study.* A Phase 2 study, SARIL-NIU-SATURN, was initiated in 2013 and is a placebo-controlled proof-of-concept study evaluating the safety and efficacy of sarilumab in non-infectious uveitis.

## ***Dupilumab (REGN668; IL-4R Antibody) for allergic and inflammatory conditions***

### Overview

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies atopic (allergic) dermatitis, asthma, chronic sinusitis with nasal polyposis, and eosinophilic esophagitis. Dupilumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R alpha subunit and block signaling from both IL-4 and IL-13.

### Atopic Dermatitis

*Phase 2b Trial.* In July 2014, we and Sanofi announced positive results from a Phase 2b dose-ranging study of dupilumab in adult patients with moderate-to-severe atopic dermatitis. All doses of dupilumab met the primary endpoint of a greater improvement in Eczema Severe Score Index (EASI) scores from baseline compared to placebo. In the Phase 2b trial, all five subcutaneous doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in EASI score from baseline to week 16. The improvements in EASI score ranged from a high of 74% for patients in the highest dose group, who received 300 mg weekly, to a low of 45% in patients who received the lowest dose of 100 mg monthly, compared to 18% for patients in the placebo group ( $p < 0.0001$  for all doses). The most common AE in the Phase 2b study was nasopharyngitis, which was balanced across dupilumab treatment groups (18.5% to 23%) compared to placebo (21%). Injection site reactions were more frequent in the dupilumab group (5% to 9.5%) compared to placebo (3%), as was headache (12% to 15%) compared to placebo (8%).

Dupilumab-treated patients showed highly statistically significant and dose-dependent improvements in additional key efficacy measures compared to placebo after 16 weeks of treatment:

- 12% to 33% of dupilumab-treated patients achieved clearing or near-clearing of skin lesions, as measured by an Investigator's Global Assessment (IGA) score of 0 or 1, compared to 2% with placebo ( $p = 0.02$  to  $p < 0.0001$ ).
- Dupilumab-treated patients experienced a 16.5% to 47% mean reduction in itching, as measured by the pruritus numerical-rating scale (NRS) score, compared to an increase of 5% in the placebo group ( $p = 0.0005$  to  $p < 0.0001$ ).

This Phase 2b double-blind, placebo-controlled, 16-week, dose-ranging study randomized 380 patients with moderate-to-severe atopic dermatitis, who could not be adequately controlled with topical medication or for whom topical treatment was not advisable. Patients were randomized to receive one of five doses of dupilumab (300 mg weekly, 300 mg every other week, 300 mg monthly, 200 mg every other week, 100 mg monthly) or placebo. Patients in the study had approximately 50% of their skin affected by atopic dermatitis at baseline. In the year preceding enrollment in the study, approximately 35% of patients received an oral corticosteroid and approximately 20% received a systemic non-steroid immunosuppressant for atopic dermatitis. Approximately 60% of patients had another allergic condition, including approximately 40% of patients who had a history of asthma. The follow-up period of the study is ongoing and patients will be followed for 16 weeks after treatment.

*Phase 3 Study.* In the fourth quarter of 2014, four Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, LIBERTY AD SOLO 2, and LIBERTY AD Open label Extension, were initiated and are currently enrolling patients. LIBERTY AD CHRONOS is a randomized, double-blind, placebo-controlled, multi-national study with the primary objective of demonstrating the efficacy of dupilumab in adults with moderate-to-severe atopic dermatitis when administered concomitantly with topical corticosteroids through 16 weeks. Secondary objectives of the LIBERTY AD CHRONOS trial will evaluate the long-term safety and efficacy of dupilumab up to 52 weeks. The LIBERTY AD Phase 3 clinical program will consist of patients with moderate-to-severe atopic dermatitis at sites worldwide.

In November 2014, the FDA granted Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. This designation is based on positive results from Phase 1 and 2 clinical trials, and the determination that atopic dermatitis is a serious disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

*Phase 2 Trial in Adolescents and Children.* In March 2015, a Phase 2 pharmacokinetic and safety study in adolescents and children (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated.

## Asthma

*Phase 2b Study.* In 2014, we and Sanofi announced positive results from the interim analysis of a dose-ranging Phase 2b study of dupilumab in adult patients with uncontrolled persistent asthma. In the study, the three highest doses of dupilumab in combination with standard-of-care therapy met the primary endpoint of a statistically significant improvement from baseline in FEV<sub>1</sub> at 12 weeks in patients with high blood eosinophils (greater than or equal to 300 cells/microliter), as compared to placebo in combination with standard-of-care therapy. In addition, two doses of dupilumab (200 mg every other week and 300 mg every other week) showed a statistically significant improvement in mean percent change in FEV<sub>1</sub>, as well as a reduction in severe exacerbations, in both the high eosinophils and overall study population. Key results included:

- In the high eosinophils patient group - mean improvements from baseline in FEV<sub>1</sub> (and mean percent change in FEV<sub>1</sub>) at 12 weeks, the primary (and a secondary) endpoint of the study were: 390 ml (26%) dupilumab 300 mg every other week (Q2W); 430 ml (26%) dupilumab 200 mg Q2W; 180 ml (10%) placebo. (p<0.01)
- In the overall population - mean improvements from baseline in FEV<sub>1</sub> at 12 weeks (and mean percent change in FEV<sub>1</sub>) were: 280 ml (18%) dupilumab 300 mg Q2W; 310 ml (18%) dupilumab 200 mg Q2W; 120 ml (6%) placebo. (p<0.001)
- In both the high eosinophils patient group and overall patient group - dupilumab showed a reduction in adjusted annualized rate of severe exacerbations compared to placebo (64% to 75% reduction, p<0.05 for high eosinophils group and p < 0.01 for the overall population)

These results were based on a pre-specified interim analysis, which occurred when all patients had reached week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.5 weeks. The final analyses on exacerbations and safety will occur at 24 weeks. The most common AE was injection site reaction, which was more frequent in the four dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common AEs in the study included upper respiratory tract infection (10% to 13% dupilumab; 13% placebo), headache (5% to 10% dupilumab; 8% placebo), nasopharyngitis (3% to 10% dupilumab; 6% placebo) and bronchitis (5% to 8% dupilumab; 8% placebo). The incidence of infections was balanced across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious AEs (3% to 7% dupilumab; 5% placebo).

The double-blind, placebo-controlled, 24-week, dose-ranging study enrolled 776 adult patients with uncontrolled persistent asthma, as defined by the Global Initiative for Asthma 2014 Guidelines. Trial participants were randomized to receive one of four doses of dupilumab (300 mg every other week, 200 mg every other week, 300 mg monthly, 200 mg monthly) or placebo. Approximately 40 percent of patients had high eosinophils across the dose groups. During the treatment period, patients continue their stable medium- or high-dose inhaled corticosteroid and long-acting beta agonist (ICS/LABA) combination product. Patients can administer inhaled rescue medication as needed during the study. A severe exacerbation event during the study is defined as a deterioration of asthma requiring the use of systemic corticosteroids for three or more days, or hospitalization or an emergency room visit. Approximately 77% of randomized patients have a history of atopic disease, which includes atopic dermatitis, allergic conjunctivitis, allergic rhinitis, chronic rhinosinusitis, nasal polyposis, food allergy, and/or hives history.

The 24-week treatment period of the study is ongoing, and patients will be followed for 16 weeks after treatment. Full results of the trial will be presented at the upcoming American Thoracic Society meeting.

*Phase 3 Study.* A Phase 3 study in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015.

## Nasal Polyps in Patients With Chronic Sinusitis

*Phase 2 Trial.* In 2013, a Phase 2 trial in NPwCS was initiated. In September 2014, we and Sanofi announced positive results from the Phase 2 proof-of-concept study of dupilumab in patients with moderate-to-severe NPwCS who did not respond to intranasal corticosteroids. The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe NPwCS. Patients in the study received 300 mg of dupilumab or placebo administered once per week subcutaneously for 16 weeks, following an initial loading dose of 600 mg. All patients in the study also received a standard-of-care nasal corticosteroid spray. Patients were eligible for the study if they continued to have severe NPwCS despite standard treatment for at least one month. Fifty percent of patients in the study had received prior surgery for their condition. Asthma was also present in 58 percent of NPwCS patients in the study. The conditions are often co-morbid and symptoms/exacerbations are frequently interdependent.

In the study, dupilumab resulted in a statistically-significant improvement in the size of nasal polyps, as measured by endoscopic Nasal Polyp Score (NPS), the primary endpoint of the study. Statistically significant improvements in all secondary efficacy endpoints were also observed, including objective measures of sinusitis by CT scan, nasal air flow, and patient-reported symptoms (sense of smell, congestion, postnasal drip, runny nose and sleep disturbance). In a pre-specified exploratory analysis, dupilumab-treated patients who also had asthma demonstrated significant improvements in asthma control. The safety profile was consistent with previous studies. The most common AEs with dupilumab were injection site reactions, nasopharyngitis, oropharyngeal pain, epistaxis, headache, and dizziness. Detailed results of the study will be presented at an upcoming medical conference.

## Eosinophilic Esophagitis

*Phase 2 Study.* A Phase 2 study of dupilumab in eosinophilic esophagitis was initiated in the first quarter of 2015. EoE is a chronic allergic inflammatory disease that is considered a major cause of gastrointestinal illness. Eosinophils are a type of white blood cell that, due to allergens, can accumulate in the esophagus, causing inflammation and tissue injuries that create difficulty swallowing. People with eosinophilic esophagitis may also have allergies, asthma, atopic dermatitis, or chronic respiratory disease.

## **Research Programs**

Our preclinical research programs are in the areas of oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

## **Research and Development Technologies**

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate EYLEA, ZALTRAP, and ARCALYST. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region," resulting in high affinity product candidates. *VelociSuite* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

***VelociSuite.*** *VelociSuite* consists of *VelocImmune*, *VelociGene*, *VelociMouse*<sup>®</sup>, and *VelociMab*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

We have utilized our *VelociSuite* technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such bi-specific antibody, which entered into clinical development in 2014, targets CD20 and CD3.

**Regeneron Genetics Center.** In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC leverages de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC utilizes laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

Central to the work of RGC is a collaboration with the Geisinger Health System of Pennsylvania. During the initial five-year collaboration term, Geisinger plans to collect samples from more than 100,000 consented patient volunteers, while RGC will perform sequencing and genotyping to generate de-identified genomic data. RGC has expanded on its foundational population-based collaboration with Geisinger with new partners with other institutions such as Columbia University Medical Center, the Clinic for Special Children, Baylor College of Medicine, and SickKids in Toronto.

## Collaboration Agreements

### Collaborations with Sanofi

**ZALTRAP.** Since September 2003, we and Sanofi have been parties to a global collaboration (ZALTRAP Collaboration Agreement) for the development and commercialization of ZALTRAP. In February 2015, we and Sanofi entered into an Amended ZALTRAP Agreement. Under the terms of the Amended ZALTRAP Agreement, Sanofi will be solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. We will also be paid for all quantities of ZALTRAP manufactured by us pursuant to a supply agreement through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation (which was approximately \$461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

**Antibodies.** Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement (each as amended). Pursuant to the collaboration, Sanofi is funding up to \$160 million per year of our antibody discovery activities over the period from 2010-2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Under our collaboration agreement, Sanofi will record product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States. We and Sanofi will equally share profits and losses from sales within the United States. We and Sanofi will share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

## Collaborations with Bayer HealthCare

**EYLEA outside the United States.** Since October 2006, we and Bayer HealthCare have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

Since inception of the agreement, we have earned \$110.0 million of development milestone payments and \$165.0 million of sales milestone payments from Bayer HealthCare. During the first quarter of 2015, we earned the final potential milestone payment under our Bayer HealthCare collaboration agreement in connection with EYLEA outside the United States.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. As a result, we expect that, initially, a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer HealthCare for this repayment obligation.

Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from any such sales.

**PDGFR-beta antibody outside the United States.** In January 2014, we entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to license and collaborate on further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a \$25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made two \$2.5 million development milestone payments to us in the first quarter of 2014. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to \$15.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare exercises its right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, continue to pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a \$20.0 million opt-in payment to us, pay a \$20.0 million development milestone to us upon receipt of the first marketing approval in the EU or Japan, share profits and losses from sales outside the United States equally with us, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, we will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

## General

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, will expand and require additional resources. We also expect to incur substantial costs related to the preparation for potential commercialization of our late-stage antibody product candidates, approximately half of which we expect to be reimbursed by Sanofi under the companies' collaboration agreement. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, and the continuation of our collaborations with Sanofi and Bayer HealthCare, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2015 to date were, and plans for the next twelve months are, as follows:

### **Trap-based Clinical Programs:**

<b>2015 Events to Date</b>	<b>2015-2016 Plans (next 12 months)</b>
<b>EYLEA</b>	
• Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD, macular edema secondary to CRVO, and DME, and continued to pursue regulatory applications for marketing approval in additional countries	• Bayer HealthCare to file for additional ex-US regulatory approvals for various indications
• European Commission approved EYLEA for the treatment of macular edema secondary to BRVO	• Regulatory agency decisions on applications outside the United States for various indications
• Bayer HealthCare submitted marketing authorization application to EMA for the treatment of mCNV	• We and Bayer HealthCare to report 3-year data from Phase 3 DME trials
• FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME	

**Antibody-based Clinical Programs:**

	<b>2015 Events to Date</b>	<b>2015-2016 Plans (next 12 months)</b>
<b><i>Praluent (PCSK9 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ BLA accepted for priority review in the United States</li> <li>ÿ Regulatory application accepted for review by the EMA</li> <li>ÿ Reported positive results from ODYSSEY CHOICE I and CHOICE II trials</li> <li>ÿ ODYSSEY LONG TERM 18-month trial results published in <i>The New England Journal of Medicine</i></li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue enrollment of Phase 3 ODYSSEY OUTCOMES trial</li> <li>ÿ Report additional results from Phase 3 ODYSSEY trials</li> <li>ÿ File for additional regulatory approvals outside the United States</li> <li>ÿ FDA and EMA decisions on regulatory applications</li> </ul>
<b><i>Sarilumab (IL-6R Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 3 MONARCH study (head-to-head monotherapy study against adalimumab)</li> <li>ÿ Initiated Phase 3 HARUKA study in Japan</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue enrollment in Phase 3 SARIL-RA program</li> <li>ÿ Complete patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis</li> <li>ÿ Report results from additional Phase 3 trials</li> <li>ÿ Submit for regulatory approval in the United States</li> </ul>
<b><i>Dupilumab (IL-4R Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 2 study in EoE</li> <li>ÿ Initiated Phase 2 study in atopic dermatitis in adolescents and children</li> <li>ÿ Initiated Phase 3 study in asthma</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in various Phase 2 and Phase 3 studies</li> <li>ÿ Initiate Phase 3 study in NPwCS</li> </ul>
<b><i>REGN1033 (GDF8 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Phase 2 proof-of-concept study in elderly men and women with sarcopenia met its primary endpoint, while secondary, functional endpoints were mixed.</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Determine future development plan</li> </ul>
<b><i>REGN1908-1909 (target not disclosed)</i></b>		<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 2 study</li> </ul>
<b><i>REGN1500 (Angptl-3 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 2 study</li> <li>ÿ On partial clinical hold by the FDA</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in Phase 1 and Phase 2 studies</li> </ul>
<b><i>REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)</i></b>	<ul style="list-style-type: none"> <li>ÿ Received Fast Track designation from the FDA for the treatment of patients with wet AMD</li> <li>ÿ Initiated Phase 2 study</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 2 study</li> </ul>
<b><i>REGN1400 (ErbB3 Antibody)</i></b>		<ul style="list-style-type: none"> <li>ÿ Determine future development plan</li> </ul>
<b><i>REGN1154 (target not disclosed)</i></b>		<ul style="list-style-type: none"> <li>ÿ Determine future development plan</li> </ul>
<b><i>REGN1193 (target not disclosed)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 study</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in Phase 1 study</li> </ul>
<b><i>REGN2222 (RSV)</i></b>	<ul style="list-style-type: none"> <li>ÿ Completed patient enrollment in Phase 1 study</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Initiate pivotal study</li> </ul>
<b><i>REGN1979 (CD20 and CD3 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Continued patient enrollment in Phase 1 study</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Complete patient enrollment in Phase 1 study</li> </ul>
<b><i>REGN910-3 (Ang2 Antibody co-formulated with EYLEA)</i></b>	<ul style="list-style-type: none"> <li>ÿ Completed patient enrollment in Phase 1 study</li> </ul>	
<b><i>REGN2810 (PD-1 Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ Initiated Phase 1 study</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Continue patient enrollment in Phase 1 study</li> </ul>
<b><i>Fasinumab (NGF Antibody)</i></b>	<ul style="list-style-type: none"> <li>ÿ On partial clinical hold by the FDA</li> </ul>	<ul style="list-style-type: none"> <li>ÿ Re-enter clinical development</li> </ul>

**Results of Operations**

The results of operations discussion below reflects certain revisions to previously-issued financial statements. See Note 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

**Three Months Ended March 31, 2015 and 2014****Net Income**

Net income for the three months ended March 31, 2015 and 2014 consists of the following:

<i>(In millions)</i>	<b>2015</b>	<b>2014</b>
Revenues	\$ 869.6	\$ 625.7
Operating expenses	(586.1)	(434.2)
Other income (expense)	(7.0)	(10.6)
Income before income taxes	276.5	180.9
Income tax expense	(200.5)	(112.6)
Net income	<u>\$ 76.0</u>	<u>\$ 68.3</u>

**Revenues**

Revenues for the three months ended March 31, 2015 and 2014 consist of the following:

<i>(In millions)</i>	<b>2015</b>	<b>2014</b>
Net product sales	\$ 544.6	\$ 362.4
Collaboration revenue:		
Sanofi	173.4	130.5
Bayer HealthCare	123.8	125.3
Total collaboration revenue	297.2	255.8
Technology licensing and other revenue	27.8	7.5
Total revenues	<u>\$ 869.6</u>	<u>\$ 625.7</u>

**Net Product Sales**

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended March 31, 2015, EYLEA net product sales increased to \$541.1 million from \$359.0 million for the three months ended March 31, 2014 due to higher sales volume. For the three months ended March 31, 2015 and 2014, we also recognized ARCALYST net product sales of \$3.5 million and \$3.4 million, respectively.

For the three months ended March 31, 2015 and 2014, we recorded 69% and 79%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

<i>(In millions)</i>	<b>Rebates &amp; Chargebacks</b>	<b>Distribution- Related Fees</b>	<b>Other Sales- Related Deductions</b>	<b>Total</b>
Balance as of December 31, 2014	\$ 3.1	\$ 21.2	\$ 0.5	\$ 24.8
Provision related to current period sales	11.4	24.7	1.4	37.5
Credits/payments	(9.8)	(13.0)	(1.4)	(24.2)
Balance as of March 31, 2015	<u>\$ 4.7</u>	<u>\$ 32.9</u>	<u>\$ 0.5</u>	<u>\$ 38.1</u>
Balance as of December 31, 2013	\$ 4.4	\$ 19.7	\$ 0.5	\$ 24.6
Provision related to current period sales	6.9	16.9	0.4	24.2
Credits/payments	(6.7)	(16.3)	(0.4)	(23.4)
Balance as of March 31, 2014	<u>\$ 4.6</u>	<u>\$ 20.3</u>	<u>\$ 0.5</u>	<u>\$ 25.4</u>

#### *Sanofi Collaboration Revenue*

The collaboration revenue we earned from Sanofi, as detailed below, primarily consisted of (i) recognition of previously deferred revenue related to our ZALTRAP Collaboration Agreement, and (ii) reimbursement for research and development expenses that we incurred, partly offset by sharing of pre-launch commercialization expenses, in connection with the companies' antibody collaboration.

<b>Sanofi Collaboration Revenue</b>	<b>Three Months Ended March 31,</b>	
<i>(In millions)</i>	<b>2015</b>	<b>2014</b>
<b>ZALTRAP:</b>		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	\$ (3.2)
Reimbursement of Regeneron research and development expenses	\$ 0.7	1.1
Other	15.2	2.2
<b>Total ZALTRAP</b>	<u>15.9</u>	<u>0.1</u>
<b>Antibody:</b>		
Reimbursement of Regeneron research and development expenses	168.8	126.8
Reimbursement of Regeneron commercialization-related expenses	8.5	—
Regeneron's share of losses in connection with commercialization of antibodies	(22.4)	—
Other	2.6	3.6
<b>Total Antibody</b>	<u>157.5</u>	<u>130.4</u>
<b>Total Sanofi collaboration revenue</b>	<u>\$ 173.4</u>	<u>\$ 130.5</u>

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in the first quarter of 2014 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales.

As described above under "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP", in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. As a result, in the first quarter of 2015 we recognized \$14.9 million of previously deferred revenue under the ZALTRAP Collaboration

Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss under the collaboration no longer exists, and (ii) the unamortized portion of up-front payments from Sanofi as we have no further performance obligations.

In the first quarter of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of \$46.0 million under our discovery agreement and \$122.8 million under our license agreement, compared to \$40.2 million and \$86.6 million, respectively, in the first quarter 2014. The higher reimbursement of development costs in the first quarter of 2015, compared to the same period in 2014, was primarily due to increased development activities for Praluent (including manufacturing pre-launch commercial supplies), dupilumab, and REGN1033.

Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' antibody collaboration agreement. Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize these antibody product candidates. In addition, we began recording our share of losses in connection with commercialization of these two antibody product candidates.

Other Sanofi antibody revenue includes recognition of deferred revenue from an \$85.0 million up-front payment and other payments. As of March 31, 2015, \$62.6 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

*Bayer HealthCare Collaboration Revenue*

The collaboration revenue we earned from Bayer HealthCare, as detailed below, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States and sales milestones achieved.

<b><u>Bayer HealthCare Collaboration Revenue</u></b> <b><i>(In millions)</i></b>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>EYLEA:</b>		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 89.4	\$ 61.2
Sales milestones	15.0	30.0
Cost-sharing of Regeneron EYLEA development expenses	2.7	20.3
Other	12.9	10.9
<b>Total EYLEA</b>	<b>120.0</b>	<b>122.4</b>
<b>PDGFR-beta antibody:</b>		
Cost-sharing of REGN2176-3 development expenses	1.3	0.5
Other	2.5	2.4
<b>Total PDGFR-beta antibody</b>	<b>3.8</b>	<b>2.9</b>
<b>Total Bayer HealthCare collaboration revenue</b>	<b>\$ 123.8</b>	<b>\$ 125.3</b>

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, and mCNV (in Japan) in the fourth quarter of 2014. In addition, in February 2015, the European Commission approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

<b><u>Regeneron's Net Profit from EYLEA Sales Outside the United States</u></b> <i>(In millions)</i>	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net product sales outside the United States	\$ 291.8	\$ 218.1
Regeneron's share of collaboration profit from sales outside the United States	103.4	75.6
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(14.0)	(14.4)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 89.4	\$ 61.2

Bayer HealthCare records revenue from sales of EYLEA outside the United States. Bayer HealthCare provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the first quarter of 2015 and 2014, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In the first quarter of 2015, we earned a \$15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding \$200 million over a twelve-month period. In the first quarter of 2014, we earned two \$15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding \$500 million and \$600 million, respectively, over a twelve-month period.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the first quarter of 2015 compared to the same period in 2014. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us \$15.7 million for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any future profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). We are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States. In addition, other EYLEA revenue includes reimbursements for producing EYLEA commercial supplies for Bayer HealthCare, and recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of March 31, 2015, \$13.1 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - PDGFR-beta antibody outside the United States." Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As of March 31, 2015, \$17.3 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

#### *Technology Licensing and Other Revenue*

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a \$165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first quarter of both 2015 and 2014, we recognized \$5.9 million of revenue related to this agreement. As of March 31, 2015, \$75.1 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded \$19.8 million of revenue primarily related to (i) manufacturing ZALTRAP commercial supplies for Sanofi and (ii) a percentage of net sales of ZALTRAP for the period from July 1, 2014 through March 31, 2015.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In the first quarter of 2015 and 2014, technology licensing and other revenue included \$2.1 million and \$1.6 million, respectively, of royalties from Novartis.

## Expenses

Total operating expenses increased to \$586.1 million in the first quarter of 2015 from \$434.2 million in the first quarter of 2014. Our average headcount in the first quarter of 2015 increased to 3,066 from 2,389 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities.

Operating expenses in the first quarter of 2015 and 2014 included a total of \$103.8 million and \$75.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the first quarter of 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

### Research and Development Expenses

Research and development expenses increased to \$343.1 million in the first quarter of 2015 from \$287.4 million in the same period of 2014. The following table summarizes the major categories of our research and development expenses:

<b>Research and Development Expenses*</b> <i>(In millions)</i>	<b>Three Months Ended March 31,</b>		<b>Increase (Decrease)</b>
	<b>2015</b>	<b>2014</b>	
Payroll and benefits <sup>(1)</sup>	\$ 116.1	\$ 96.0	\$ 20.1
Clinical trial expenses	56.2	48.2	8.0
Clinical manufacturing costs <sup>(2)</sup>	88.8	58.2	30.6
Research and other development costs	25.9	27.8	(1.9)
Occupancy and other operating costs	29.2	27.4	1.8
Cost-sharing of Bayer HealthCare and Sanofi development expenses <sup>(3)</sup>	26.9	29.8	(2.9)
<b>Total research and development expenses</b>	<b>\$ 343.1</b>	<b>\$ 287.4</b>	<b>\$ 55.7</b>

\* Certain prior year amounts have been reclassified to conform to the current year's presentation.

<sup>(1)</sup> Includes Non-cash Compensation Expense of \$50.2 million for the three months ended March 31, 2015 and \$37.6 million for the three months ended March 31, 2014.

<sup>(2)</sup> Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of \$9.3 million for the three months ended March 31, 2015 and \$5.7 million for the three months ended March 31, 2014.

<sup>(3)</sup> Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse. Our collaborators provide us with estimated development expenses for the most recent fiscal quarter. Bayer HealthCare and Sanofi's estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter, and our portion of our collaborators' development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to additional costs for clinical studies of dupilumab and early-

stage antibody product candidates, partly offset by lower Praluent- and EYLEA-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of Praluent. Cost-sharing of Bayer HealthCare and Sanofi development expenses primarily consists of costs related to our obligation to fund 20% of Sanofi's Phase 3 Praluent and sarilumab development costs, which commenced during the fourth quarter of 2013.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare and Sanofi's development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

<b>Project Costs</b> <i>(In millions)</i>	<b>Three Months Ended</b> <b>March 31,</b>		<b>Increase</b> <b>(Decrease)</b>
	<b>2015</b>	<b>2014</b>	
Praluent	\$ 81.6	\$ 53.5	\$ 28.1
Dupilumab	54.6	43.1	11.5
Sarilumab	18.1	19.4	(1.3)
EYLEA	19.4	33.4	(14.0)
Other antibody candidates in clinical development	61.0	43.8	17.2
Other research programs and unallocated costs	108.4	94.2	14.2
<b>Total research and development expenses</b>	<b>\$ 343.1</b>	<b>\$ 287.4</b>	<b>\$ 55.7</b>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3b and 4 studies. Phase 3b studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

### *Selling, General, and Administrative Expenses*

Selling, general, and administrative expenses increased to \$159.0 million in the first quarter of 2015 from \$103.2 million in the first quarter of 2014 primarily due to higher costs associated with the Branded Prescription Drug Fee, higher headcount and related costs, and higher Non-cash Compensation Expense principally for the reason described under "Expenses" above, partly offset by lower contributions to not-for-profit organizations that assist patients with chronic disease conditions. Selling, general, and administrative expenses included \$42.2 million and \$32.0 million of Non-cash Compensation Expense in the first quarter of 2015 and 2014, respectively.

### *Cost of Goods Sold*

Cost of goods sold was \$42.6 million in the first quarter of 2015 and \$27.5 million in the first quarter of 2014. Cost of goods sold, which primarily consists of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies, increased principally due to the increase in U.S. EYLEA net product sales.

### *Cost of Collaboration and Contract Manufacturing*

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare, increased to \$41.4 million in the first quarter of 2015 from \$16.1 million in the first quarter of 2014. This increase was primarily due to royalties payable to Genentech in connection with higher sales of EYLEA outside the United States, as well as the recognition of costs associated with commercial supplies of ZALTRAP. Under our collaboration arrangements, when the product is sold by our collaborators to third-party customers, our risk of inventory loss no longer exists, and we therefore recognize our related manufacturing costs for the sold product as cost of collaboration manufacturing. However, as described above, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi. As a result, in the first quarter of 2015 we recognized as expense \$20.2 million of previously inventoried costs for ZALTRAP commercial supplies that were shipped to Sanofi because our risk of inventory loss no longer exists under the Amended ZALTRAP Agreement.

### *Other Income and Expense*

Total other expenses (net of other income) decreased to \$7.0 million in the first quarter of 2015 from \$10.7 million in the first quarter of 2014. Interest expense in the first quarter of 2015 and 2014 primarily includes interest associated with our 1.875% convertible senior notes (the Notes), including amortization of the note discount and debt issuance costs, and interest associated with our facility lease obligations. Interest expense in the first quarter of 2015 decreased compared to the first quarter of 2014 primarily due to \$237.3 million principal amount of our convertible senior notes which were surrendered for conversion since the first quarter of 2014. In addition, in the first quarter of 2015, we recognized a \$0.9 million loss in connection with \$6.7 million principal amount of our Notes which were surrendered for conversion during the first quarter of 2015.

### *Income Taxes*

In the first quarter of 2015 and 2014, we recorded income tax expense of \$200.5 million and \$112.6 million, respectively. The effective tax rate was 72.5% and 62.2% for the first quarter of 2015 and 2014, respectively. The first quarter 2015 effective tax rate was negatively impacted by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities.

The effective tax rate for the first quarter of 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, and (iii) New York state tax legislation enacted in the first quarter of 2014. The tax legislation reduced the New York state income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the reduction of our related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in our effective tax rate by 10.4% for the first quarter of 2014.

### *Liquidity and Capital Resources*

The sources and uses of cash discussion below reflects certain revisions to previously-issued financial statements. See Note 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

### *Sources and Uses of Cash for the Three Months Ended March 31, 2015 and 2014*

As of March 31, 2015, we had \$1,225.5 million in cash, cash equivalents, and marketable securities compared with \$1,360.6 million as of December 31, 2014. Additionally, as of March 31, 2015, we had borrowing availability of \$750.0 million under a revolving credit facility that was entered into during the first quarter of 2015 (see further description under "Credit Facility" below).

### *Cash (Used in) Provided by Operating Activities*

Net cash used in operating activities was \$87.5 million in the first quarter of 2015. Our net income of \$76.0 million in the first quarter of 2015 included Non-cash Compensation Expense of \$103.8 million and depreciation and amortization of \$16.0 million. In addition, deferred tax assets as of March 31, 2015 increased by \$10.9 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by a reduction in deferred revenue.

As of March 31, 2015, Sanofi, Bayer HealthCare, and trade accounts receivable increased by \$321.1 million, compared to December 31, 2014, primarily due to higher trade accounts receivable resulting from lengthened payment terms to certain of our U.S. EYLEA customers effective mid-2014. Prepaid expenses and other assets as of March 31, 2015 decreased by \$35.9 million, compared to December 31, 2014, primarily due to a decrease in prepaid taxes used to offset current taxes payable. Our deferred revenue as of March 31, 2015 decreased by \$16.1 million, compared to December 31, 2014, primarily due to (i) recognition of previously deferred ZALTRAP revenue related to amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP, and (ii) amortization of a previously received and deferred \$165.0 million payment under our license agreement with Astellas, partly offset by higher deferred revenue in connection with manufacturing commercial supplies of EYLEA for Bayer HealthCare, which is deferred until the product is sold by Bayer HealthCare to third-party customers. Accounts payable, accrued expenses, and other liabilities increased by \$25.5 million as of March 31, 2015, compared to December 31, 2014, primarily due to (i) higher income taxes payable and (ii) accruals for sales-related charges (including the impact of the Branded Prescription Drug Fee), deductions, and royalties related to EYLEA, partly offset by (iii) lower payroll-related liabilities as our year-end 2014 employee cash bonuses were paid in the first quarter of 2015.

Net cash provided by operating activities was \$53.5 million in the first quarter of 2014. Our net income of \$68.3 million in the first quarter of 2014 included the following non-cash expenses: (i) Non-cash Compensation Expense of \$75.8 million, (ii) depreciation and amortization of \$11.5 million, and (iii) non-cash interest expense of \$5.9 million, primarily resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes. In addition, deferred tax assets as of March 31, 2014 increased by \$5.8 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense and deferred revenue, partly offset by the reduction of our deferred tax assets related to the New York State tax legislation enacted in the first quarter of 2014, which reduced our New York State income tax rate to zero percent effective in 2014.

As of March 31, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable increased by \$92.5 million, compared to December 31, 2013, primarily due to higher trade accounts receivable in connection with U.S. EYLEA product sales, higher amounts receivable from Sanofi in connection with reimbursement of our antibody development costs, and higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by \$15.6 million, compared to December 31, 2013, primarily in connection with increased production of EYLEA commercial supplies. Prepaid expenses and other assets increased by \$20.9 million, compared to end-of-year 2013, primarily due to higher prepaid sales-related fees. Our deferred revenue as of March 31, 2014 decreased by \$37.1 million, compared to December 31, 2013, primarily due to (i) the receipt of a \$25.5 million upfront payment as well as two \$2.5 million non-substantive development milestone payments in connection with our PDGFR-beta antibody collaboration agreement with Bayer HealthCare, and (ii) higher deferred revenue in connection with manufacturing commercial supplies of EYLEA for Bayer HealthCare. This revenue is deferred until the product is sold by Bayer HealthCare to third-party customers. These increases were partly offset by amortization of a previously received and deferred \$165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities decreased by \$14.1 million as of March 31, 2014, compared to December 31, 2013, primarily due to lower payroll-related liabilities as our year-end 2013 employee cash bonuses were paid in the first quarter of 2014 and lower liabilities for vendor invoices received but not yet paid, partly offset by higher accruals for sales-related charges.

### *Cash Used in Investing Activities*

Net cash used in investing activities was \$129.5 million and \$236.2 million in the first quarter of 2015 and 2014, respectively. In the first quarter of 2015 and 2014, purchases of marketable securities exceeded sales or maturities by \$15.3 million and \$171.4 million, respectively. Capital expenditures were \$114.2 million and \$64.8 million in the first quarter of 2015 and 2014, respectively. Capital expenditures in the first quarter of 2015 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility and tenant improvement and associated costs related to two new buildings under construction at our leased Tarrytown, New York facilities. Capital expenditures in the first quarter of 2014 primarily included costs in connection with purchasing manufacturing equipment, expanding our Rensselaer, New York manufacturing facilities, and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

### *Cash Provided by Financing Activities*

Net cash provided by financing activities was \$76.2 million and \$109.0 million in the first quarter of 2015 and 2014, respectively. In the first quarter of 2015, \$16.7 million principal amount of our Notes that was previously surrendered for conversion was settled. In accordance with the terms of the Notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted notes, and shares of our Common Stock in respect of any amounts due in excess thereof. Also during the first quarter of 2015, we paid an aggregate amount of \$124.5 million to a warrant holder to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were \$76.3 million in the first quarter of 2015, compared to \$55.0 million in the first quarter of 2014. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock were \$21.2 million in the first quarter of 2015 compared to \$63.1 million in the first quarter of 2014. Cash flows from financing activities also increased by \$155.6 million and \$117.3 million in the first quarter of 2015 and 2014, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

### *Credit Facility*

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a \$750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to \$250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a \$100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of March 31, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit Facility as of March 31, 2015.

### *Tarrytown, New York Lease*

In April 2013, we entered into a new lease agreement for approximately 297,000 square feet of additional new laboratory and office space to be constructed in two new buildings (the Buildings), which are expected to be completed in the second half of 2015, at our current Tarrytown, New York location. The term of the lease, which commenced during the second half of 2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which are expected to commence in the second half of 2015 and will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses. Based upon various factors, including our involvement in the Buildings' construction and our responsibility for directly paying for a substantial portion of tenant improvements, we are deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of Financial Accounting Standards Board (FASB) authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, we capitalize the landlord's costs of constructing these new facilities, offset by a corresponding facility lease obligation. In addition, we recognize, as additional facility lease obligation, reimbursements from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation. We will allocate a portion of our future lease payments to the Buildings and the land on which the Buildings are being constructed. The land element of the lease is treated for accounting purposes as an operating lease. As of March 31, 2015 and December 31, 2014, the Buildings' facility lease obligation balance was \$170.6 million and \$152.8 million, respectively.

## **Capital Expenditures**

Our cash expenditures for property, plant, and equipment totaled \$114.2 million in the first quarter of 2015 and \$64.8 million in the first quarter of 2014 (as described above under "*Cash Used in Investing Activities*" above). In addition, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York location for an aggregate purchase price of \$73.0 million. We intend to develop this property to accommodate and support our growth, primarily in connection with expanding our existing research and development and office space.

We expect to incur capital expenditures of approximately \$535 million to \$635 million during the last three quarters of 2015 primarily in connection with renovating our new Limerick, Ireland facility, tenant improvements primarily related to the two new buildings under construction at our leased Tarrytown, New York facilities, expanding and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility, and purchase of the land described above.

## **Funding Requirements**

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, costs related to the preparation for potential commercialization of our late-stage antibody product candidates, and commercialization of EYLEA. We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and funding for reimbursement of development costs that we are entitled to receive under our collaboration agreements will enable us to meet our projected operating needs for the foreseeable future. As described above, research and development expenses that we incur in connection with our antibodies collaboration are generally funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed antibody drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. In addition, as described above, we and Bayer HealthCare share (i) agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration, and (ii) development costs under the initial development plan in connection with our PDGFR-beta antibody collaboration.

Under our collaboration agreements with Sanofi and Bayer HealthCare, we and our collaborator share profits and losses in connection with commercialization of drug products. Profits or losses under each collaboration are measured by calculating net sales less cost of goods sold and shared commercialization and other expenses. If the applicable collaboration is profitable, we have contingent contractual obligations to reimburse Sanofi and, in connection with EYLEA outside the United States, Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by Sanofi and Bayer HealthCare, respectively. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our EYLEA collaboration with Bayer HealthCare, our percentage on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. In particular, as of December 31, 2014, our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately \$262 million. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales of EYLEA outside the United States will be used to reimburse our collaborator for this obligation.

We enter into research collaboration and licensing agreements that may require us to pay amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant. For example, in May 2013, we acquired from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications; consequently, we are obligated to pay up to \$30.0 million in potential additional development milestones as well as royalties on any future sales of PDGF antibodies. Additionally, if required by the agreement, we may be required to make royalty payments calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted.

The amount we need to fund operations will depend on various factors, including revenues from net product sales, the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with Sanofi and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above.

Our commercialization costs over the next few years will depend on, among other things, whether or not our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on sales of commercial products. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay additional royalties or share the profits from such sales pursuant to our license or collaboration agreements. In addition, under the provisions of the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010, the Branded Prescription Drug Fee is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. This fee is allocated to companies, including Regeneron, based on their market share of total branded prescription drug sales into these government programs.

As described above, in the first quarter of 2015 and 2014, we made cash payments of \$21.2 million and \$63.1 million, respectively, for employee tax obligations in connection with stock option exercises and vesting of restricted stock. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises and the sales prices of our Common Stock, and may continue to be substantial.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will be substantial.

In April 2015, we received notification that an additional \$127.3 million principal amount of our Notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2015. We elected to settle these conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, we exercised a proportionate amount of our Note hedges, for which we expect to receive shares of Common Stock equivalent to the number of shares we will be required to issue to settle the non-cash portion of the related Note conversions. In future periods, other holders of these debt securities may surrender their Notes for conversion.

We may also from time to time seek to repurchase or retire our outstanding Notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise.

Due primarily to the amounts of our tax credit carry-forwards available for tax purposes, which totaled approximately \$143 million as of December 31, 2014, and potential excess tax benefits in connection with stock option exercises, we expect our cash income tax payments for 2015 to be significantly less than the income tax expense recorded in our financial statements in 2015, which is based on an effective tax rate.

In connection with our PDGFR-beta antibody agreement with Bayer HealthCare, we are eligible to receive up to \$15.0 million in future development milestone payments from Bayer HealthCare (representing 50% of the development milestone payments potentially due to Sanofi as described above), although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration. Furthermore, if Bayer HealthCare exercises their right to opt-in to the collaboration, they will be obligated to pay a \$20.0 million opt-in payment to us, and pay a \$20.0 million development milestone to us upon receipt of the first marketing approval in the EU or Japan. During the first quarter of 2015, we earned our final sales milestone payment (\$15.0 million) from Bayer HealthCare in connection with sales of EYLEA outside in the United States.

### **Future Impact of Recently Issued Accounting Standards**

In May 2014, the FASB issued a new standard related to revenue recognition, *Revenue from Contracts with Customers*, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. The new standard will be effective for interim and annual reporting periods beginning after December 15, 2016, and early adoption is not permitted. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. We have not yet determined our method of transition and are evaluating the impact that this guidance will have on our financial statements.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures Around Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (filed February 12, 2015). There have been no material changes to our market risks or to our management of such risks as of March 31, 2015.

## ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described in our Annual Report on Form 10-K for the year ended December 31, 2014 (filed February 12, 2015) and those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part II, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity," "Regulatory and Litigation Risks," and "Risks Related to Our Common Stock."

#### *Proceedings Relating to '287 Patent and '018 Patent*

As previously reported, we had sued Merus B.V., a company based in Utrecht, The Netherlands, for infringement of our European Patent No. 1,360,287 in the District Court of The Hague and for infringement of our U.S. Patent No. 8,502,018 (the '018 Patent) in the United States District Court for the Southern District of New York. Both of these patents concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent infringement litigation, in which it effectively found that Merus did not infringe the '018 Patent and held the '018 Patent invalid. On December 19, 2014, we petitioned the court to enter a final judgment so that we could appeal the court's ruling. On January 15, 2015, the court declined to enter a final judgment on infringement and validity, resulting in our inability to appeal the court's ruling at this time.

### ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

#### **Risks Related to Commercialization of EYLEA**

***We are substantially dependent on the success of EYLEA. If we or Bayer HealthCare are unable to continue to commercialize EYLEA, our business, prospects, operating results, and financial condition will be materially harmed.***

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the three months ended March 31, 2015 and 2014, EYLEA net sales in the United States represented 62% and 57% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer HealthCare were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer HealthCare are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

***We are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we fail to maintain regulatory compliance for EYLEA, we may lose marketing approval, which would materially harm our business, prospects, operating results, and financial condition.***

We are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA for its currently approved indications in the United States, EU, and other countries where the product is approved. If we fail to maintain regulatory compliance for EYLEA for its currently approved indications, we may lose marketing approval, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - *If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales*" below.

***Serious complications or side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition.***

There are risks inherent in intravitreal injections, including intravitreal injections with EYLEA, such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and other side effects, all of which are reported from time to time to the FDA. Serious complications or serious, unexpected side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition.

***Our sales of EYLEA are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.***

Our sales in the United States of EYLEA are dependent, in part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

***The commercial success of EYLEA is subject to strong competition.***

The market for eye disease products is very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis<sup>®</sup> (ranibizumab), for the treatment of wet AMD, macular edema following RVO, DME, visual impairment due to mCNV, diabetic retinopathy in patients with DME, and other eye indications. Lucentis<sup>®</sup> was approved by the FDA in June 2006 for the treatment of wet AMD, in June 2010 for the treatment of macular edema following RVO (including CRVO and BRVO), in August 2012 for the treatment of DME, and in February 2015 for the treatment of diabetic retinopathy in patients with DME. Lucentis<sup>®</sup> was also approved by the EMA for wet AMD in January 2007, for DME in January 2011, for the treatment of macular edema following RVO (including CRVO and BRVO) in June 2011, and for mCNV in July 2013. Competitors are also exploring the development of a biosimilar version of Lucentis<sup>®</sup>; in particular, Pfenex Inc. is developing PF582, which is currently in a Phase 1b/2a trial in patients with wet AMD. Other competitive or potentially competitive products include Allergan's Ozurdex<sup>®</sup> (dexamethasone intravitreal implant) (approved by the FDA in June 2009 for the treatment of macular edema following RVO and in September 2014 for the treatment of DME) and Alimera Sciences' Iluvien<sup>®</sup> (fluocinolone acetonide intravitreal implant) (approved by the FDA in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids.

Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, in January 2012, Genentech submitted an IND for such an extended delivery device. Novartis is developing ESBA1008 (RTH258), a humanized monoclonal single-chain Fv (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated a non-inferiority Phase 3 trial comparing RTH258 (ESBA1008) and EYLEA in December 2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin<sup>®</sup>) for wet AMD and related conditions and a Phase 2 trial has been completed. Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation is developing Fovista<sup>™</sup>, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista<sup>™</sup>, including Lucentis<sup>®</sup> + Fovista<sup>™</sup>, Avastin<sup>®</sup> (bevacizumab) + Fovista<sup>™</sup>, and EYLEA + Fovista<sup>™</sup>. Genentech initiated a Phase 1 trial of a bi-specific antibody targeting both VEGF and Ang2 for wet AMD.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin<sup>®</sup>, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin<sup>®</sup> in patients with wet AMD presents a significant competitive challenge in this indication. Competitors (including Amgen) are also developing a biosimilar version of Avastin<sup>®</sup>. Long-term, controlled clinical trials comparing Lucentis<sup>®</sup> to Avastin<sup>®</sup> in the treatment of wet AMD are being conducted. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) were reported in April 2011 and indicated that Avastin<sup>®</sup> dosed monthly was non-inferior to Lucentis<sup>®</sup> dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Two-year data from CATT were reported in April 2012 and indicated that monthly Avastin<sup>®</sup> was non-inferior to monthly Lucentis<sup>®</sup> in mean visual acuity gain; as-needed dosing was *not* non-inferior to monthly dosing. Avastin<sup>®</sup> is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other countries. Furthermore, Lucentis<sup>®</sup> and off-label use of repackaged Avastin<sup>®</sup> present significant competitive challenges as doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of repackaged Avastin<sup>®</sup> in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it may be approved. Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. See also "Risks Related to Commercialization of Products - *We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects*" below.

***Our product sales could be reduced by imports from countries where our products are available at lower prices.***

Our sales of products in the United States may be reduced if our products are imported into the United States from lower priced markets, whether legally or illegally. Under our arrangement with Bayer HealthCare, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer HealthCare. Prices for EYLEA in territories outside the United States will be based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and our sales of EYLEA in the United States may be reduced if EYLEA marketed in those nations is imported into the United States (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. These practices are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports of our products may exert pressure on the pricing of our products in a particular market or reduce our or our collaborators' sales, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues could be reduced.

## Risks Related to the Development and Approval of Our Product Candidates and New Indications for Our Marketed Products

***If we do not obtain and maintain regulatory approval for our products and product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.***

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates, or new indications of our marketed products, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. If we are unable to obtain regulatory approval for our product candidates, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition may be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA's currently approved indications, we may lose marketing approval and the ability to generate EYLEA product sales revenue, which would materially and negatively impact our business, prospects, operating results, and financial condition.

***Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.***

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a ten-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within 6 months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation (including based on the rare pediatric disease priority review voucher, which we and Sanofi used in connection with the BLA submission for Praluent), we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, prospects, operating results, and financial condition may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

***Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.***

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

***Successful development of our current and future product candidates is uncertain.***

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. For example, a randomized, double-blind Phase 3 trial (VENICE) that evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone did not meet the pre-specified criterion of improvement in overall survival in April 2011. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

***Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.***

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

EYLEA is being studied in diseases of the eye in addition to those covered by its currently approved indications. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA, which can cause injury to the eye and other complications. For example, in our Phase 3 trials of EYLEA in wet AMD,

the most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. These and other complications or side effects could harm the development and/or commercialization of EYLEA.

We and Sanofi are conducting a global development program, currently in Phase 3, studying Praluent, our PCSK9 antibody for the reduction of LDL cholesterol, as discussed above in Part I, Item 1. "Business - Late-Stage Antibody-based Clinical Programs." As part of this development program, we and Sanofi collect adverse events and report them to the FDA and foreign regulatory authorities. As previously reported, in ten Phase 3 ODYSSEY studies, the most common adverse events were nasopharyngitis and upper respiratory tract infection, which were generally balanced between treatment groups. Injection site reactions were more frequent in the Praluent group compared to placebo. Serious adverse events and deaths were generally balanced between treatment groups as were other key adverse events, including musculoskeletal, neurocognitive, and liver-related events. We and Sanofi were advised by the FDA that it had become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. The FDA had requested that we and Sanofi make an assessment of potential neurocognitive adverse events across the global development program for Praluent, especially in the longer-term studies. Additionally, the FDA requested that we address the feasibility of incorporating neurocognitive testing into at least a subset of patients in our ODYSSEY OUTCOMES trial or other long-term Phase 3 trial(s). While we have reported, based on analyses conducted to date, that neurocognitive adverse events were generally balanced between treatment groups in our Phase 3 studies, if this or another adverse event signal is detected in future analyses or in subsequent data, the possible approval of Praluent may be delayed or fail, or its commercial value diminished, which could severely harm our future prospects.

We have studied fasinumab in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the FDA placed fasinumab on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company's anti-NGF program due to the FDA's concern that this case was suggestive of a class effect. In December 2012, the FDA removed the clinical hold on fasinumab after reviewing our proposed Phase 3 program in osteoarthritis. However, shortly thereafter, fasinumab was placed on partial clinical hold as a result of preclinical data from other investigational agents targeting NGF in development. There are currently no trials with fasinumab that are either enrolling or treating patients. Discussions with the FDA about fasinumab are expected to continue.

***Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.***

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

***We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.***

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

***If approved, some of our product candidates may be used with drug delivery devices, which have their own regulatory and other risks.***

If approved, some of our product candidates (such as Praluent) may be used in combination with a drug delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. The success of our product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application, our product candidates used with such drug delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. In addition, some of these drug delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our

collaborators, or third-party providers, or failure of our company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

### **Risks Related to Intellectual Property and Market Exclusivity**

***If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.***

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 1,360,287 has been the subject of opposition proceedings in the European Patent Office, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014. We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review under the America Invents Act of 2011. We expect that post-grant review proceedings will become common in the United States and will be costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

***We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving our patents. For example, we are currently parties to patent infringement proceedings initiated by us relating to our European Patent No. 1,360,287 and our U.S. Patent No. 8,502,018, both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014 and Part II, Item 1. "Legal Proceedings" of this report. In addition, we are currently parties to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent, the antibody to PCSK9 for LDL cholesterol reduction we are jointly developing with Sanofi, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2014. We are aware of additional patents and pending applications owned by others that claim antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies. We are also aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R and IL-4R and methods of treating rheumatoid arthritis and uveitis and atopic dermatitis and asthma with such antibodies. In addition to Praluent, our late-stage antibody-based pipeline includes sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis and non-infectious uveitis; and dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, chronic sinusitis with nasal polyposis, and eosinophilic esophagitis. Although we do not believe that any of our late-stage antibody product candidates infringes any valid claim in these patents or patent applications, these other parties could initiate a lawsuit for patent infringement and assert their patents are valid and cover our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. We are also aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST nor EYLEA is a recombinant antibody. If any of our antibody product candidates are produced in a manner subject to valid claims

in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to make recombinant antibodies in, or to import them into, the United States. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our drug candidates, or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

***Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.***

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under *"If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed,"* the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of biosimilar versions of biological products. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

## Risks Related to Manufacturing and Supply

***We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA, to commercialize our other product candidates or other indications for our marketed products if they receive regulatory approval, and to advance our clinical pipeline.***

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, ZALTRAP, and ARCALYST, and (b) our antibody product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody product candidates, our current manufacturing capacity will likely not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

***Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.***

We have commenced construction of additional manufacturing space at our Rensselaer, New York site to increase our manufacturing capacity. In addition, we have acquired and are renovating a 400,000 square foot facility in Limerick, Ireland to expand our manufacturing capacity to support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, the Limerick, Ireland facility remains subject to securing certain permits from the local government, and there is no guarantee that we will be able to obtain the remaining required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA and ARCALYST and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

***Our ability to manufacture products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.***

Our ability to continue to manufacture EYLEA, ZALTRAP, and ARCALYST in our Rensselaer, New York facilities and, in the future, our ability to manufacture our marketed products at additional facilities, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products to which those intellectual property rights apply, which could materially harm our business, prospects, operating results, and financial condition.

***If sales of EYLEA do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties.***

We have large-scale manufacturing operations in Rensselaer, New York. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

***Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.***

We currently manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and product candidates are biologics, they require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our corporate collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

***If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.***

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

## **Risks Related to Commercialization of Products**

***We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.***

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payers, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

Currently, we have two marketed products, EYLEA and ARCALYST. While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, our commercialization experience is still relatively limited and we have no sales, marketing, commercial, or distribution capabilities outside the United States. In addition, EYLEA faces intense competition from Lucentis® and from off-label use of repackaged Avastin®, both of which have been on the market for a number of years and, potentially, from new competitive products currently in clinical development. We expect that the continued commercial success of EYLEA will depend on many factors, including the following:

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;

- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis<sup>®</sup>, and the willingness of retinal specialists and patients to switch from Lucentis<sup>®</sup> or off-label use of repackaged Avastin<sup>®</sup> to EYLEA;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development; and
- the effect of existing and new health care laws and regulations currently being implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices.

Under the terms of our license and collaboration agreement with Bayer HealthCare, we rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer HealthCare are unsuccessful in continuing to commercialize EYLEA, our ability to sustain profitability would be materially impaired. In addition, if we or our collaborators are unable to successfully commercialize new product candidates or new indications for our marketed product, our future prospects would be materially impaired.

***Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.***

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve commercialization of our product candidates, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

The market for eye disease products is very competitive, as described in greater detail above under "Risks Related to Commercialization of EYLEA - *The commercial success of EYLEA is subject to strong competition.*"

Our earlier stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune* technology. Our antibody generation technologies and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in partnership with Eli Lilly), Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra<sup>®</sup>) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Alder Biopharmaceuticals, Ablynx (in partnership with AbbVie), and Pfizer have antibodies against IL-6 or IL-6R in clinical development. Several companies, including Amgen, Pfizer, and Eli Lilly, have development programs for antibodies against PCSK9. Amgen's PCSK9 program appears to be the most advanced of the competitors, having already submitted a BLA with the FDA and a marketing authorization application with the EMA, and may obtain marketing approval in one or more countries before our PCSK9 antibody is approved. Alnylam, in partnership with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including an oral product. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent (if approved). Certain late-stage inhibitors of cholesterylester transfer protein (CETP), such as Merck's anacetrapib and Eli Lilly's evacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for Praluent. Another oral agent that lowers LDL-C and that may potentially compete with Praluent, if approved, is Esperion's ETC-1002. A number of companies are developing antibodies that, if approved, may compete with dupilumab, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-13), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in partnership with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). For muscle-wasting conditions, Pfizer, Eli Lilly, Bristol-Myers Squibb, and Atara Biotherapeutics have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

***The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition.***

Our future revenues and profitability will be adversely affected in a material manner if United States and foreign governmental payers, private third-party insurers and payers (such as health maintenance organizations and pharmacy benefit management companies), and other third-party payers, including Medicare and Medicaid, do not adequately defray or reimburse the cost of our products to the patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our products, we must, among other things, maintain registration of the products in the National Drug Code registry, maintain our re-labeler license, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by CMS and other federal and state agencies. Further, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label, repackaged Avastin<sup>®</sup> rather than Lucentis<sup>®</sup> for the treatment of wet AMD. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since EYLEA for its currently approved indications will likely continue to be too expensive for most patients to afford without health insurance coverage, if third-party payers, including Medicare and Medicaid in the United States, do not continue to provide adequate coverage and reimbursement for EYLEA, our ability to successfully market it would be materially adversely impacted. There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement

of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

***We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.***

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the three months ended March 31, 2015 and 2014, we recorded 69% and 79%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

## **Regulatory and Litigation Risks**

***If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.***

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

***If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.***

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services

reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

As part of the PPACA, the federal government has enacted provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made or distributed to prescribers and other healthcare providers. These statutory provisions and related regulations (commonly known as the "Sunshine Act") require pharmaceutical manufacturers to report annually to the Secretary of the U.S. Department of Health and Human Services payments or other transfers of value made to physicians or teaching hospitals. In February 2013, regulations were released that contain detailed guidance regarding the information that must be collected and reported. We started to be required to collect information regarding such payments in August 2013 and submitted our 2013 Reporting Entity and Payment Aggregate Data in June 2014, as required by the Sunshine Act. Over the next several years, we will need to dedicate significant resources to enhance our systems and processes in order to comply with these regulations. The PPACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. Many of these requirements and standards are new and uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition.

***Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.***

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

***Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.***

As a biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

***Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.***

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, a number of which have yet to be fully implemented. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

***Changes in laws and regulations affecting the healthcare industry could adversely affect our business.***

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

***Risks associated with our operations outside of the United States could adversely affect our business.***

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- our ability to deploy overseas funds in an efficient manner;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

***We may incur additional tax liabilities related to our operations.***

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The Internal Revenue Service or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, the availability of the U.S. research and development tax credit, and changes in tax laws and regulations.

***We face potential liability related to the privacy of health information we obtain from research institutions and our collaborators.***

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, is collaborating with the Geisinger Health System, which is subject to such regulations, and may enter into collaboration arrangements with additional institutions in the future. Regeneron is not a HIPAA-covered entity and our clinical research efforts are not directly regulated by HIPAA, so we are not subject to civil penalties under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it, may apply to some or all of the clinical data obtained from our collaborators outside of the U.S. Failure by those collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

***Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.***

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

## Risks Related to Our Reliance on Third Parties

***If our antibody collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.***

We rely heavily on funding from Sanofi to support our target discovery and antibody research and development programs. Sanofi has committed to pay up to \$160 million per year, or a total of \$1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as Praluent, sarilumab, and dupilumab, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts out of their development, unless we enter into a collaboration agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab and REGN2222, and decided not to opt in to the REGN1154, REGN1193, REGN1500, and other programs. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

***If our collaboration with Bayer HealthCare for EYLEA is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed.***

We rely heavily on Bayer HealthCare to assist with the development, and the commercialization outside the United States, of EYLEA. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA development program. As the EYLEA program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEA development program, continue to lead the development of EYLEA outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare's Japanese affiliate. We cannot assure you that regulatory approvals will be received for EYLEA in additional indications outside the United States or that EYLEA will be successfully commercialized outside the United States. If Bayer HealthCare and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA outside the United States and result in substantial additional costs to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States.

***Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.***

We depend upon third-party collaborators, including Sanofi, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of EYLEA for its currently approved indications, ARCALYST for the treatment of CAPS, and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, GLPs, or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We rely on third-party service providers to support the distribution of EYLEA in the United States and for many other related activities in connection with the commercialization of this marketed product. Despite our arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, our sales of EYLEA will suffer.

#### **Risk Related to Employees**

***We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.***

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos, M.D., Ph.D., President, Regeneron Laboratories and our Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA and begin to commercialize other products assuming the receipt of required regulatory approvals, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

#### **Information Technology Risks**

***Significant disruptions of information technology systems or breaches of data security could adversely affect our business.***

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

#### **Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing**

***If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.***

Beginning in the first quarter of 2012, we reported profitability; prior to that, we generally incurred net losses. If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, and our share of the profits from Bayer HealthCare's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

***We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the ongoing marketing of EYLEA and the anticipated commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody product candidates we are developing on our own (without Sanofi), and expenses related to the requirement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. Our ability to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we are able to obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of EYLEA, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

***Changes in foreign currency exchange rates could have a material adverse effect on our operating results.***

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our company.

***Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.***

As of March 31, 2015, we had \$507.9 million in cash and cash equivalents and \$717.6 million in marketable securities (including \$89.6 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

## **Risks Related to Our Common Stock**

***Our stock price is extremely volatile.***

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- fluctuations in our operating results, in particular net product sales of EYLEA;

- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA;
- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been increasing its ownership of our Common Stock. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

***Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.***

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 16, 2015, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 16, 2015. As of April 16, 2015, Sanofi beneficially owned 22,859,144 shares of our Common Stock, representing approximately 22.6% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our discovery and preclinical development agreement with Sanofi relating to our antibody collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. In July 2014, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase additional shares of our Common Stock to progressively increase its beneficial ownership in 2014 and 2015 up to the maximum allowed under the “standstill” provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

***Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.***

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 16, 2015, holders of Class A Stock held 16.3% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 16, 2015:

- our current executive officers and directors beneficially owned 10.3% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 16, 2015, and 21.9% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 16, 2015; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 50.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 16, 2015. In addition, these five shareholders plus our Chief Executive Officer held approximately 55.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 16, 2015.

Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our company, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

In addition, upon Sanofi reaching 20% ownership of our then outstanding shares of Class A Stock and Common Stock (taken together), we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our then outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our then outstanding

shares of Class A Stock and Common Stock (taken together). This designee is required to be "independent" of our company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. In April 2014, Sanofi notified us that it had reached the 20% ownership threshold and designated Robert A. Ingram as its designee. On April 4, 2014, following recommendation of the Corporate Governance and Compliance Committee, the board of directors elected Mr. Ingram as a director and a member of the Compensation Committee. Mr. Ingram was subsequently elected as a Class I director at our 2014 Annual Shareholder Meeting for a term expiring at the 2016 Annual Shareholder Meeting.

***The convertible note hedges and warrant transactions we entered into in connection with our convertible senior notes issuance may affect the trading price of our Common Stock.***

In connection with our offering of our 1.875% convertible senior notes due October 1, 2016, we entered into convertible note hedge transactions with four financial institutions (the hedge counterparties), the purpose of which was to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes (as applicable) upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments (as applicable) as required under the convertible note hedge documents, we would not receive the benefit of such transactions. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants. As of March 31, 2015, an aggregate principal amount of \$162.7 million of the notes and 3,122,015 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock and could have the effect of increasing or preventing a decline in the value of our Common Stock during any cash settlement averaging period related to a conversion of the notes.

In addition, we intend to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind their hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares of our Common Stock.

***The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our convertible senior notes and related warrant and hedge transactions, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.***

Our restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder", a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*"

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our license and collaboration agreement with Sanofi relating to our antibody collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2014 PDGFR-beta license and collaboration agreement with Bayer HealthCare, Bayer HealthCare is prohibited from seeking to influence the control of our company or acquiring more than 20% of our then outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our company; (iii) the acquisition (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our then outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer HealthCare; (v) other specified events, such as a liquidation or dissolution of our company.

The holders of our convertible senior notes have fundamental change purchase rights, which require us to purchase all or a portion of their notes upon the occurrence of a fundamental change, as defined in the indenture governing the notes. In addition, the indenture contains provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes. These rights and provisions may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors. In addition, upon the occurrence of certain extraordinary events, the hedge transactions would be exercised upon the conversion of notes, and the warrant transactions may be terminated. It is possible that the proceeds we receive upon the exercise of the convertible note hedge transactions would be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. Such differences may result in the acquisition of us being on terms less favorable to our shareholders than it would otherwise be.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer provide for severance benefits in the event of termination as a result of a change in control of our company. Also, stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan and our 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plans. Further, under the amended and restated investor agreement between us and Sanofi, we are required under certain circumstances to appoint an individual agreed upon by us and Sanofi to our board of directors, as described above under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*" These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

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

In the first quarter of 2015, we settled the conversion of \$16.7 million principal amount of our 1.875% convertible senior notes through the payment of \$16.7 million in cash (equal to the principal amount of the converted notes) and issuance of 146,253 shares of our Common Stock to the holders of the Notes surrendered for conversion. We issued and sold the notes in October 2011 in a private placement in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. In connection with this conversion, we exercised a proportionate amount of our convertible note hedges, as a result of which we received from our hedge counterparties 146,248 shares of our Common Stock.

**Issuer Purchases of Equity Securities**

The following table reflects shares of Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan or the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan in the first quarter of 2015.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
3/1/2015-3/31/2015	5,157	\$ 476.50	—	—

**ITEM 6. EXHIBITS**

(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
10.1*	Amended and Restated Collaboration Agreement, dated as of February 23, 2015, by and between Sanofi-Aventis US LLC and Regeneron Pharmaceuticals, Inc. (the "Registrant").
10.2	Third Amendment, dated as of February 17, 2015, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant.
10.3	(a) Credit Agreement, dated as of March 19, 2015, by and among the Registrant, as a borrower and guarantor; certain direct and indirect subsidiaries of the Registrant, as the initial subsidiary borrowers; JPMorgan Chase Bank, N.A., as administrative agent; Bank of America, N.A. and U.S. Bank National Association, as co-syndication agents; Barclays Bank PLC, Citibank, N.A., Credit Suisse AG, Cayman Islands Branch, Fifth Third Bank and Morgan Stanley MUFG Loan Partners, LLC, as co-documentation agents; JPMorgan Chase Bank, N.A., Bank of America, N.A. and U.S. Bank National Association, as the issuing banks; JPMorgan Chase Bank, N.A., as the swingline lender; and the other lenders party thereto from time to time.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

\* Portions of this document have been omitted and filed separately with the Securities and Exchange Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

(a) Incorporated by reference to Exhibit 10.1 to the Form 8-K for the Registrant, filed March 23, 2015.

**SIGNATURE**

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.

REGENERON PHARMACEUTICALS, INC.

Date: May 7, 2015

By: /s/ Robert E. Landry

Robert E. Landry  
Senior Vice President, Finance and  
Chief Financial Officer  
(Duly Authorized Officer)

Confidential Treatment has been requested for the redacted portions of this agreement. The redactions are indicated with four asterisks [\*\*\*\*]. A complete version of this agreement has been filed separately with the Securities and Exchange Commission.

AMENDED AND RESTATED COLLABORATION AGREEMENT

By and Between

SANOFI-AVENTIS US, LLC

and

REGENERON PHARMACEUTICALS, INC.

Dated as of February 23, 2015

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## AMENDED AND RESTATED COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED COLLABORATION AGREEMENT (“Agreement”), dated as of February 23, 2015 (the “Amendment Execution Date”), amends and restates, effective as of July 1, 2014 (the “Amendment Effective Date”) the Collaboration Agreement, dated as of September 5, 2003 (the “Effective Date”), as amended, by and between Sanofi-Aventis US, LLC (as successor in interest to Aventis Pharmaceuticals Inc.), a corporation organized under the laws of Delaware and having a principal place of business at 55 Corporate Drive, Bridgewater, NJ 08807 (“Aventis”), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 (“Regeneron”) (with each of Aventis and Regeneron referred to herein individually as a “Party” and collectively as the “Parties”).

WHEREAS, Regeneron has developed certain VEGF inhibitor molecules referred to herein as VEGF Trap Products, and Regeneron and Aventis have collaborated on the development and commercialization of certain VEGF Trap Products in the Territory; and

WHEREAS, Regeneron and Aventis wish to amend this Agreement in part and terminate this Agreement in part so that Aventis has the right to continue to commercialize the Licensed Product and to develop the Licensed Product for additional oncology indications on revised financial and other terms, and the rights to other VEGF Products and other indications shall revert to Regeneron all as set forth herein.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**ARTICLE 1**  
**DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 “Actual Fully Burdened Manufacturing Cost” shall have the meaning set forth in Schedule 11.

1.2 “Additional Major Market Country” shall mean any country in the Territory, other than the Major Market Countries referred to in clause (a) of the definition thereof, in which Net Sales in the immediately prior Contract Year were [\*\*\*\*] or more of aggregate Net Sales in the Territory and such designation shall remain effective from and after January 1 of such Contract Year and each Contract Year thereafter as long as Net Sales in such country in the immediately preceding Contract Year(s) are [\*\*\*\*] or more of aggregate Net Sales in the Territory in such Contract Year(s). Notwithstanding the foregoing, the Parties shall have the right to mutually agree that a country that exceeds [\*\*\*\*] aggregate Net Sales threshold in a given Contract Year shall not be an Additional Major Market Country if such country is not expected to exceed such [\*\*\*\*] aggregate Net Sales threshold on an ongoing basis.

1.3 “Affiliate” shall mean, with respect to any Person, any other Person that controls, is controlled by or is under common control with such first Person. A Person shall be deemed to control another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such first Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case 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. For purposes of this Agreement, in no event shall Aventis or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Aventis or any of its Affiliates.

1.4 “Aggregate Actual Fully Burdened Manufacturing Cost” shall have the meaning set forth in Section 9.7(c).

1.5 “Aggregate Profit Sharing Payment” shall have the meaning set forth in Section 9.6(b).

1.6 “Agreement” shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.7 “Amendment Effective Date” shall have the meaning set forth in the introductory paragraph.

1.8 “Amendment Execution Date” shall have the meaning set forth in the introductory paragraph.

1.9 “Ancillary Agreement” shall mean the Supply Agreement and the Investor Agreement.

1.10 “Approval” shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the testing, manufacture, Development, Commercialization, sale, storage or transport of, or expanded labeling for, such Licensed Product in any country, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.11 “Assigned Regeneron Regulatory Documentation” has the meaning set forth in Section 7.1.

1.12 “Aventis” shall have the meaning set forth in the introductory paragraph.

1.13 “Aventis Know-How” shall mean (a) all Know-How that is conceived, developed, created or otherwise made by or on behalf of Aventis (or its Affiliates or its or their sublicensees or Distributors) under or in connection with this Agreement during the Term (or any transition period as provided in Schedule 6 or Schedule 7), and (b) all Know-How that (i) is Controlled as of the Effective Date and at any time during the Term by Aventis or any of its Affiliates (other than by operation of the license and other grants in ARTICLE 4) and (ii) relates to a VEGF Trap, in each case ((a) and (b)), excluding any Joint Inventions. Aventis Know-How shall include New Information of Aventis.

1.14 “Aventis Indemnitees” shall have the meaning set forth in Section 17.1(b).

1.15 “Aventis Intellectual Property” shall mean the Aventis Patent Rights and Aventis Know-How.

1.16 “Aventis Patent Rights” shall mean (a) those Patents Controlled as of the Effective Date or hereafter during the Term by Aventis or any of its Affiliates (other than by operation of the license in ARTICLE 4) that include at least one claim that would be infringed by the manufacture, use, sale, offer for sale or import of any VEGF Product and (b) those Patents that (i) claim or cover the Aventis Know-How and (ii) are Controlled by Aventis or any of its Affiliates (other than by operation of the license and other grants in ARTICLE 4).

1.17 “Aventis Sole Inventions” shall have the meaning set forth in Section 12.1(a).

1.18 “Aventis Trademarks” shall have the meaning set forth in Section 11.3.

1.19 “Batch” shall have the meaning set forth in the Supply Agreement.

1.20 “Batch Number” shall have the meaning set forth in Section 9.7(c).

1.21 “BLA” shall mean, with respect to each Licensed Product, a biologics license application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside of the United States.

1.22 “Business Day” shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

1.23 “Calendar Quarter” shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1 during the Term, except that for purposes of ARTICLE 9 the first Calendar Quarter shall commence on the Amendment Effective Date and shall end on December 31, 2014 and the last Calendar Quarter shall end on the last day of the Term.

1.24 “Clinical Supply Requirements” shall mean, with respect to a Licensed Product, the quantities of such Licensed Product that are required by Aventis (a) for Development, including the conduct of pre-clinical studies and Clinical Trials in connection with the Development Plan in order to obtain Approval of such Licensed Product in the Field in any country in the Territory and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in any country in the Territory or (b) for any Non-Approval Trial.

1.25 “Clinical Trial” shall mean any clinical trial conducted for the purpose of or which results in obtaining data to support or be included in a Registration Filing, including any clinical trial conducted or sponsored by a Party’s medical affairs department which is referenced in a BLA solely in connection with an integrated safety database.

1.26 “CMC” shall mean chemistry, manufacturing and controls.

1.27 “Collaboration Purpose” has the meaning set forth in Section 5.6.

1.28 “Commercial Supply Requirements” shall mean, with respect to each Licensed Product, quantities of such Licensed Product as are required by Aventis to fulfill Aventis’ requirements for commercial sales and product sampling with respect to such Licensed Product in the Field in the Territory or any country in the Territory, as the case may be.

1.29 “Commercialize” or “Commercialization” shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, commercializing, offering for sale, having sold and/or selling a Licensed Product, including sampling and conducting Non-Approval Trials.

1.30 “Commercialization Plan” has the meaning set forth in Section 6.2.

1.31 “Commercially Reasonable Efforts” shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose, and substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it, which product is at a similar stage in its development or product life and is of similar market potential. Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitive factors. It is anticipated that the level of effort will change over time. In determining whether a Party has used Commercially Reasonable Efforts, the payments made or required to be made hereunder or under the Supply Agreement shall not be factors weighed (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must make any payments hereunder or under the Supply Agreement). In determining whether Aventis has used Commercially Reasonable Efforts with respect to the Commercialization of Licensed Products, a failure by Regeneron to satisfy its obligations to supply Formulated Bulk Licensed Product pursuant to Section 3.1 of the Supply Agreement, to the extent amounts supplied by Regeneron are insufficient to meet the Commercial Supply Requirements of Licensed Product, shall be a relevant factor to take into account; *provided, however*, that, for clarity, in no event shall this sentence apply with respect to Aventis’ obligations under Section 8.2.

1.32 “Contract Year” shall mean the period beginning on the Effective Date and ending on December 31, 2003, and each succeeding twelve (12) month period thereafter during the Term, except that the last Contract Year shall end on the last day of the last Calendar Quarter.

1.33 “Control” means, with respect to any item of New Information or Party Information, material, regulatory documentation, Patents or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under such New Information or Party Information, material, regulatory documentation, Patents or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.34 “Controlling Party” shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that primarily claims a VEGF Product (or the making or use thereof, including, without limitation, any devices for the administration of such VEGF Product or any component thereof), and Aventis in the case of all other Joint Patent Rights.

1.35 “CPI” shall mean the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.36 “CPI Adjustment” shall mean the percentage increase or decrease, if any, in the CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made.

1.37 “Cumulative Net Sales” shall have the meaning set forth in Section 9.6(c).

1.38 “Damages” shall have the meaning set forth in Section 17.1(a).

1.39 “Default Interest Rate” shall have the meaning set forth in Section 9.10.

1.40 “Develop” or “Development” shall mean (a) activities directly and specifically relating to the pre-clinical and clinical drug development of a Licensed Product, including, without limitation, test method development, stability testing with respect to Licensed Product manufactured by or on behalf of Aventis (for clarity, other than Product supplied by Regeneron pursuant to the Supply Agreement), assay development, toxicology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development, pharmacokinetic studies, Clinical Trials (including research to design Clinical Trials and develop target product profiles), regulatory affairs, drug safety surveillance activities, and Approvals, (b) any other research and development activities with respect to a Licensed Product and (c) any pre-launch marketing activities (including, without limitation, market research and analysis, and health economics) performed prior to First Commercial Sale of such Licensed Product.

1.41 “Development Balance” has the meaning set forth in this Agreement prior to the Amendment Execution Date.

1.42 “Development Plan” shall have the meaning set forth in Section 5.2.

1.43 “Distributor” shall mean any Third Party contractually engaged by Aventis to distribute the Licensed Products in a country in the Territory (other than the United States).

1.44 “Effective Date” shall have the meaning set forth in the introductory paragraph.

1.45 “EMA” shall mean the European Medicines Agency or any successor agency thereto.

1.46 “Estimated Fully Burdened Batch Price” shall have the meaning set forth in Section 9.7(b).

1.47 “Excluded Ocular Field” shall mean all local administration of any VEGF Product to the eye, including by topical, intravitreal, periorbital, implants or other means, for the treatment or diagnosis of any ocular disease or disorder.

1.48 “Excluded Ocular VEGF Products” shall mean any VEGF Product delivered via local administration to the eye, including by topical, intravitreal, periorbital, implants or other means.

1.49 “Excluded Rights” has the meaning set forth in Section 4.6.

1.50 “Executive Officers” shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer or Chief Operating Officer of Aventis.

1.51 “Existing Licenses” shall mean the agreements listed in Schedule 1.

1.52 “EYLEA Drug Substance” means the biological compound aflibercept.

1.53 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

1.54 “Field” means (a) oncology (other than for treatments using local administration to the eye, including by topical, intravitreal, periorbital, implants or other means) and (b) other indications (other than the Excluded Ocular Field) as may be mutually agreed by the Parties in writing.

1.55 “Finished Licensed Product” shall mean Licensed Product in its finished, labeled and packaged form, ready for sale to the market.

1.56 “Firm Order” shall have the meaning set forth in the Supply Agreement.

1.57 “First Commercial Sale” shall mean the first sale of any Licensed Product, following receipt of Marketing Approval, by a Party or one of its Affiliates, or its or their sublicensees or Distributors to a Third Party in the relevant country in the Territory, as the case may be, on arm’s length commercial terms. Sales for test marketing, Clinical Trial or Non-Approval Trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

1.58 “Force Majeure” shall have the meaning set forth in ARTICLE 18.

1.59 “Formulated Bulk Licensed Product” shall mean the Licensed Products formulated into solution, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.60 “FTE” shall mean a full time equivalent employee (i.e. one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [\*\*\*\*] hours per year.

1.61 “Funded Assets MOU” shall mean that certain memorandum of understanding and agreement by and between Regeneron and sanofi-aventis U.S., LLC, dated May 7, 2008.

1.62 “GAAP” shall mean generally accepted accounting principles in the United States.

1.63 “Genentech Settlement Agreement” shall mean that certain Non-Exclusive License and Settlement Agreement between Genentech, Inc., Regeneron, Sanofi U.S. Services, Inc., and sanofi-aventis U.S. LLC, dated as of May 17, 2013.

1.64 “Genentech Settlement Letter” shall mean that certain letter agreement by and between Regeneron, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC, dated May 17, 2013, pursuant to which Regeneron, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC allocated responsibility for certain amounts payable to Genentech, Inc. under the Genentech Settlement Agreement.

1.65 “Good Practices” shall mean compliance with the applicable standards contained in then-current “Good Laboratory Practices,” “Good Manufacturing Practices” and/or “Good Clinical Practices,” as promulgated by the FDA and all analogous guidelines promulgated by the EMA, ICH or other country regulatory agencies, as applicable.

1.66 “Governmental Authority” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.67 “IAS/IFRS” shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.68 “ICH” shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.69 “IND” shall mean, with respect to each Licensed Product, an Investigational New Drug Application filed with the FDA with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside of the United States.

1.70 “Indemnified Party” shall have the meaning set forth in Section 17.2(a).

1.71 “Indemnifying Party” shall have the meaning set forth in Section 17.2(a).

1.72 “Infringement” shall have the meaning set forth in Section 13.1(a).

1.73 “Investor Agreement” has the meaning set forth in Section 19.6. The Investor Agreement shall constitute an Ancillary Agreement.

1.74 “Joint Intellectual Property” shall mean Joint Patent Rights and Joint Inventions.

1.75 “Joint Inventions” shall have the meaning set forth in Section 12.1(b).

1.76 “Joint Patent Rights” shall mean Patents that cover a Joint Invention.

1.77 “Joint ZALTRAP Committee” or “JZC” shall have the meaning set forth in Section 3.1.

1.78 “Know-How” shall mean any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings, and other information (whether or not patentable or otherwise protected by trade secret Law).

1.79 “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority in the Territory.

1.80 “Lead Litigation Party” shall have the meaning set forth in Section 13.1(b).

1.81 “Legal Dispute” shall mean any dispute, controversy or claim related to compliance with this Agreement or the Supply Agreement or the validity, breach, termination or interpretation of this Agreement or the Supply Agreement, including any dispute with respect to whether (a) the Development Plan or a proposed amendment thereto does not constitute Commercially Reasonable Efforts or otherwise satisfy Aventis’ obligations under this Agreement with respect to a Licensed Product; (b) Aventis has used Commercially Reasonable Efforts to Develop, and obtain and maintain Approvals for, the Licensed Products in the Field in the Territory and carry out the Development activities assigned to it in the Development Plan pursuant to Section 5.1; or (c) Aventis has used Commercially Reasonable Efforts to Commercialize the Licensed Products throughout the Territory pursuant to Section 6.1.

1.82 “Licensed Compound” means the biological compound ziv-aflibercept.

1.83 “Licensed Product” means any product that is comprised of or contains the Licensed Compound as the sole active ingredient, but excluding any Excluded Ocular VEGF Products.

1.84 “Litigation Party” shall have the meaning set forth in Section 13.1(b).

1.85 “[\*\*\*\*] Facility” shall mean the facility owned by [\*\*\*\*] located in [\*\*\*\*].

1.86 “Major Market Country” shall mean any of the Original Major Market Countries and any of the Additional Major Market Countries.

1.87 “Marketing Approval” shall mean Approval required for the marketing and sale of a Licensed Product in a country in the Territory.

1.88 “Modified Clause” shall have the meaning set forth in Section 20.7.

1.89 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of Licensed Products in the Field in the Territory by Aventis, its Affiliates, or its or their sublicensees or Distributors to Third Parties (other than sublicensees or Distributors), less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the United States) consistently applied:

- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Products;
- (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
- (c) chargebacks and other amounts paid on sale or dispensing of the Licensed Products;
- (d) Third Party cash rebates and chargebacks related to sales of the Licensed Products, to the extent allowed;
- (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory refunds, credits and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;
- (g) freight, postage, shipment and costs (or wholesale fees in lieu of those costs) and customs duties incurred in delivering Licensed Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Licensed Products, which are separately identified on the invoice or other documentation; and
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Products falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 9.9. Sales between Aventis and its Affiliates, or its or their sublicensees or Distributors for resale shall be disregarded for purposes of calculating Net Sales unless such purchaser is an end user of the Licensed Product. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales, but that are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by Aventis or its Affiliate, as applicable.

1.90 “New Information” shall mean any and all ideas, inventions, information, data, writings, discoveries, improvements, or materials not generally known to the public that arise or are conceived or developed by (a) either Party or its Affiliates or (b) the Parties or their Affiliates jointly, in each case ((a) and (b)) under or in connection with this Agreement or any Ancillary

Agreement during the Term and to the extent specifically related to any VEGF Products, including, without limitation, information and data included or referenced in the Registration Filings made under this Agreement and any Approvals.

1.91 “New License” shall mean any license entered into by a Party (or its Affiliates) with a Third Party after the Amendment Execution Date, other than Existing Licenses, required for the manufacture, development or commercialization of any VEGF Product in such Party’s respective field (*i.e.*, with respect to Aventis, the Field, and with respect to Regeneron, outside of the Field). For clarity, any New License (as defined in this Agreement prior to the Amendment Execution Date) entered into prior to the Amendment Execution Date shall constitute an Existing License.

1.92 “Non-Approval Trial” shall mean any clinical trial of a Licensed Product in the Field in the Territory other than a Clinical Trial.

1.93 “Out-of-Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates.

1.94 “Original Major Market Country” shall mean any of [\*\*\*\*].

1.95 “Party” or “Parties” shall have the meaning set forth in the introductory paragraph.

1.96 “Party Information” shall mean, with respect to a Party, all ideas, inventions, information, data, writings, discoveries, improvements, or materials not generally known to the public (in each case, other than New Information) that are provided to or made available in connection with this Agreement or any Ancillary Agreement by either Party or their respective Affiliates to the other Party or its Affiliates whether furnished before or after the Effective Date, including, without limitation, information and materials in relation to research, development, manufacturing, promotion, marketing, distributing and selling of VEGF Products hereunder, and information and materials on substances, formulations, techniques, technology, equipment, data, reports, Know-How, sources for supply, patent position, business plans, sales management procedures and other general business and operational processes and procedures. With respect to each Party, Party Information does not include New Information.

1.97 “Patents” shall mean (a) all national, regional and international patents and patent applications, including, without limitation, provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including, without limitation, divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including, without limitation, utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, revalidations, reissues, re-examinations and extensions (including any

supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including, without limitation, so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.98 “Payment Total” shall have the meaning set forth in Section 9.7(c).

1.99 “Period Costs” shall have the meaning set forth in Schedule 11.

1.100 “Person” shall mean and include an individual, partnership, joint venture, limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.

1.101 “[\*\*\*\*] Product” shall mean a biopharmaceutical product that [\*\*\*\*].

1.102 “Plan” shall mean any Development Plan or Commercialization Plan.

1.103 “Pricing Approval” shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where governmental authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.104 “Product” shall have the meaning set forth in the Supply Agreement.

1.105 “Product Trademark” shall mean, with respect to each Licensed Product, the trademark selected by Aventis for use on such Licensed Product and/or accompanying logos, trade dress and/or other indicia of origin, in each case as selected by Aventis.

1.106 “Profit Sharing Payment” shall have the meaning set forth in Section 9.6(b).

1.107 “Promotional Materials” shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.108 “Publishing Party” shall have the meaning set forth in Section 16.3.

1.109 “Reconciliation Amount” shall have the meaning set forth in Section 9.7(c)(i).

1.110 “Regeneron” shall have the meaning set forth in the introductory paragraph.

1.111 “Regeneron Costs” shall mean, with respect to any (a) activity that is requested or authorized by Aventis in writing, (b) activity that relates to the Development, manufacture or Commercialization of the Licensed Product and is requested or otherwise recommended by a Regulatory Authority, including activities in connection with obtaining and maintaining

Regulatory Approvals for the Licensed Products in the Field in the Territory, (c) pharmacovigilance activity that is related to the Licensed Products, (d) activity that relates to the stability testing of the Licensed Products, and (e) Period Costs, in each case ((a), (b), (c), (d) and (e)), (y) all Out-of-Pocket Costs and (z) an amount equal to the product of (i) the number of FTEs required for such activity and (ii) the Regeneron FTE Rate. For clarity, the Regeneron Costs shall not include any costs or expenses otherwise included in Actual Fully Burdened Manufacturing Costs.

1.112 “Regeneron FTE Rate” shall mean (a) in Contract Year 2014, US\$[\*\*\*\*] (b) in Contract Year 2015, US\$[\*\*\*\*], and (c) in Contract Year 2016 and subsequent Contract Years, the rate in the prior Contract Year adjusted as of January 1 of Contract Year 2016 and each such subsequent Contract Year by the CPI Adjustment.

1.113 “Regeneron Indemnitees” shall have the meaning set forth in Section 17.1(a).

1.114 “Regeneron Intellectual Property” shall mean the Regeneron Patent Rights and the Regeneron Know-How.

1.115 “Regeneron Know-How” shall mean (a) all Know-How that is conceived, developed, created or otherwise made by or on behalf of Regeneron (or its Affiliates or its or their sublicensees or Distributors) under or in connection with this Agreement during the Term, and (b) all Know-How that (i) is Controlled as of the Effective Date and at any time during the Term by Regeneron or any of its Affiliates (other than by operation of the license and other grants in ARTICLE 4) and (ii) relates to a VEGF Trap, in each case ((a) and (b)), excluding any Joint Inventions. Regeneron Know-How shall include New Information of Regeneron.

1.116 “Regeneron Licensed Product Domain Names” shall mean those domain names that are Controlled by Regeneron or its Affiliates as of the Effective Date that are set forth on Schedule 9.

1.117 “Regeneron Patent Rights” shall mean (a) those Patents Controlled as of the Effective Date or hereafter during the Term by Regeneron or any of its Affiliates (other than by operation of the license in ARTICLE 4) that include at least one claim that would be infringed by the manufacture, use, sale, offer for sale or import of any Licensed Product and (b) those Patents that (i) claim or cover the Regeneron Know-How and (ii) are Controlled by Regeneron or any of its Affiliates (other than by operation of the license and other grants in ARTICLE 4).

1.118 “Regeneron Sole Inventions” shall have the meaning set forth in Section 12.1(a).

1.119 “Regeneron Trademarks” shall have the meaning set forth in Section 11.2.

1.120 “Registration Filing” shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any testing, marketing authorization application, supplementary application or variation thereof, IND, BLA, or any equivalent applications in any country.

1.121 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, marketing, pricing, reimbursement and/or sale of any VEGF Product in a country in the Territory, including, without limitation, the FDA in the United States and EMA in Europe.

1.122 “Sole Inventions” shall have the meaning set forth in Section 12.1(a).

1.123 “Supply Agreement” shall have the meaning set forth in Section 8.1.

1.124 “Supply Term” shall mean the Term of the Supply Agreement, as defined in the Supply Agreement.

1.125 “SWI” shall mean Sanofi Withrop Industrie or such other Affiliate of Aventis that is a party to the Supply Agreement.

1.126 “Term” shall have the meaning set forth in Section 19.1(a).

1.127 “Terminated Territory” means each country with respect to which this Agreement is terminated by Aventis pursuant to Section 19.2(a) or, if this Agreement is terminated in its entirety, the entire Territory.

1.128 “Termination Notice Period” shall have the meaning set forth in Section 19.2.

1.129 “Territory” shall mean all the countries of the world, other than the Terminated Territory.

1.130 “Third Party” shall mean any Person other than Aventis or Regeneron or any Affiliate of either Party.

1.131 “Third Party Claim” shall have the meaning set forth in Section 17.1(a).

1.132 “Third Party Payment Amount” shall mean, with respect to a period, the royalties and other amounts payable to a Third Party with respect to the manufacture, Development or Commercialization of a Licensed Product in the Field in the Territory in such period under any Existing License or New License to which Regeneron is a party, other than the Genentech Settlement Agreement.

1.133 “United States” or “U.S.” shall mean the United States of America (including its territories and possessions and its military bases and commissaries wherever located in the Territory) and Puerto Rico.

1.134 “VEGF Products” shall mean [\*\*\*\*].

1.135 “VEGF Trap” shall mean [\*\*\*\*].

1.136 “VEGF Trap Product” shall mean any pharmaceutical products for human and/or animal use which includes VEGF Trap as an active ingredient, alone or in combination with one or more other active ingredients, for any and all indications.

## ARTICLE 2

### GENERAL

2.1 Compliance With Law. Both Aventis and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in an effort to Develop, manufacture, and Commercialize Licensed Products in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.2 Commercially Reasonable Efforts. Subject to the terms of this Agreement, each Party (and its Affiliates) shall use Commercially Reasonable Efforts to fulfill all responsibilities assigned to it under this Agreement and any then-applicable Plans.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use all Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement, and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements.

(a) Aventis agrees to comply with the obligations set forth in (i) the Existing Licenses or the New Licenses to which it is a party and to notify Regeneron of any terms or conditions in any such Existing License or New License with which Regeneron is required to comply as a licensee or sublicensee, as the case may be, and (ii) any other material agreement to which Aventis is a party and that is related to the development, manufacture or commercialization of VEGF Products, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder, in each case ((i) and (ii)), as necessary to preserve the rights granted to Regeneron and the obligations assumed by Aventis under this Agreement with respect to VEGF Products inside and outside the Field in the Territory. Moreover, Aventis shall (A) take all actions reasonably necessary to ensure Aventis' compliance

with (1) any such terms and conditions of any Existing License or New License with which Aventis is required to comply as a licensee or sublicensee, as the case may be, and (2) any such material agreement referred to in clause (ii) above and (B) not terminate or amend any Existing License, New License or any other material agreement referred to in clause (ii) above, in each case, without the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed, if such termination or amendment would impose any material liability or restriction on Regeneron with respect to the development, manufacture or commercialization of VEGF Products (other than Licensed Products in the Field in the Territory) in the Territory.

(b) Regeneron agrees to comply with the obligations set forth in (i) the Existing Licenses or the New Licenses to which it is a party and to notify Aventis of any terms or conditions in any such Existing License or New License with which Aventis is required to comply as a licensee or sublicensee, as the case may be, and (ii) any other material agreement to which Regeneron is a party and that is related to the Development, manufacture or Commercialization of Licensed Products in the Field in the Territory, including, without limitation, and subject to Section 9.4, any obligations to pay royalties, fees or other amounts due thereunder, in each case ((i) and (ii)), as necessary to preserve the rights granted to Aventis and the obligations assumed by Regeneron under this Agreement with respect to Licensed Products in the Field in the Territory. Moreover, Regeneron shall (A) take all actions reasonably necessary to ensure Regeneron's compliance with (1) any such terms and conditions of any Existing License or New License with which Regeneron is required to comply as a licensee or sublicensee, as the case may be, and (2) any such material agreement referred to in clause (ii) above and (B) not terminate or amend any Existing License, New License or any other material agreement referred to in clause (ii) above, in each case, without the prior written consent of Aventis, such consent not to be unreasonably withheld or delayed, if such termination or amendment would impose any material liability or restriction on Aventis with respect to the Development, manufacture or Commercialization of Licensed Products in the Field in the Territory.

(c) Notwithstanding anything in this Agreement to the contrary, Aventis shall not be permitted to enter into any New License pursuant to which it obtains rights to VEGF Products outside of the Field in the Territory and Regeneron shall not be permitted to enter into any New License pursuant to which it obtains rights to VEGF Products in the Field in the Territory, in each case, without the prior written consent of the other Party.

2.5 Plans. Aventis shall undertake all Development and Commercialization activities in accordance with approved Plans. The Parties may agree to amend all Plans from time to time as circumstances may require pursuant to the terms of this Agreement.

### **ARTICLE 3 JOINT ZALTRAP COMMITTEE**

3.1 Joint ZALTRAP Committee. Within thirty (30) days after the Effective Date, the Parties shall establish a joint ZALTRAP committee (the "Joint ZALTRAP Committee" or "JZC"), which shall have the following responsibilities:

(a) coordinating the Parties' (or its Affiliates') activities under the Supply Agreement, including the sharing of information between the Parties with respect to Regeneron's Available Capacity and Aventis's projected Clinical Supply Requirements and Commercial Supply Requirements;

(b) coordinating the exchange and review of the Development Plan, the Commercialization Plan and any Development or Commercialization reports described in Sections 5.4 and 6.3 between the Parties;

(c) coordinating any activities to be performed by the Parties as described in ARTICLE 5 and ARTICLE 6; and

(d) coordinating the Parties' regulatory activities and interactions with Regulatory Authorities pursuant to ARTICLE 7.

### 3.2 Composition; Meetings.

(a) The JZC shall be comprised of senior representatives from each of Aventis and Regeneron, selected by such Party. The exact number of representatives of each Party shall be as determined by such Party; *provided, however*, that neither Party shall appoint more than three (3) representatives to serve on the JZC. A Party may change any of its representatives at any time by giving written notice to the other Party.

(b) The JZC shall have two co-chairpersons, one designated by each of Aventis and Regeneron. The co-chairpersons of the JZC shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; and (ii) required to call emergency meetings of the JZC at the request of a Party. The JZC co-chairpersons shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JZC meetings, which meeting minutes shall be submitted for approval of the members of the JZC.

(c) The JZC shall meet whenever any member of the JZC shall make such a request in writing to the co-chairpersons; *provided, however*, that the JZC shall in no event meet less frequently than every six (6) months. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member of the JZC to attend meetings where appropriate (e.g., representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed to be members of the JZC, nor shall they have any rights or responsibilities of a member of the JZC.

(d) In the event of a dispute within the JZC regarding any matter governed by the dispute resolution provisions of Sections 5.1, 5.2 or 6.1, either Party may refer such dispute to the Executive Officers for resolution pursuant to the provisions of Sections 5.1, 5.2 or 6.1, as applicable.

3.3 Limitations on Authority. The JZC shall not have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified as provided in Section 20.5 or compliance with which may only be waived as provided in Section 20.2.

#### **ARTICLE 4 LICENSE GRANTS**

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement and any license agreement within the Regeneron Patent Rights, Regeneron hereby grants to Aventis and its Affiliates the nontransferable (except as permitted by Section 20.9), exclusive (including with regard to Regeneron and its Affiliates except as provided in this Section 4.1 and Section 4.2) right and license, with the right to grant sublicenses in accordance with Section 4.3, under the Regeneron Intellectual Property and Regeneron's interest in the Joint Intellectual Property to make, have made, import, use, sell and offer for sale the Licensed Products solely for use in the Field in the Territory; *provided, however*, that Regeneron reserves for itself and its Affiliates and its and their Third Party licensees the non-exclusive right under the Regeneron Intellectual Property and Regeneron's interest in the Joint Intellectual Property to make, have made and use the Licensed Compound and Licensed Products for research and development purposes in the Field in the Territory. For clarity, the foregoing proviso shall not grant Regeneron rights under the Regeneron Intellectual Property and Regeneron's interest in the Joint Intellectual Property to sell or offer for sale the Licensed Products in the Field in the Territory. The foregoing license grant shall not preclude Regeneron from, and Regeneron retains all rights with respect to, using or otherwise exploiting, or granting any Person the right to use or otherwise exploit, Regeneron Intellectual Property and Regeneron's interest in the Joint Intellectual Property for the making, having made, importing, using, selling and offering for sale (a) the Licensed Compound and Licensed Products solely for use outside the Field in the Territory and (b) products (other than Licensed Products) for use with Licensed Products in the Field in the Territory.

4.2 Aventis License Grants. Subject to the terms and conditions of this Agreement and any license agreement within the Aventis Patent Rights, Aventis hereby grants to Regeneron and its Affiliates (a) a fully paid-up, royalty-free, worldwide, exclusive (including with regard to Aventis and its Affiliates) right and license, with the right to grant sublicenses through multiple tiers, under the Aventis Intellectual Property and Aventis' interest in the Joint Intellectual Property to make, have made, import, use, sell and offer for sale (i) the Licensed Compound and Licensed Products solely for use in the Excluded Ocular Field worldwide and (ii) VEGF Products (other than Licensed Products) worldwide and (b) a fully paid-up, royalty-free, worldwide, non-exclusive right and license, with the right to grant sublicenses through multiple tiers, under the Aventis Intellectual Property and Aventis' interest in the Joint Intellectual Property to make, have made, import, use, sell and offer for sale products (other than Licensed Products) for use with Licensed Products in the Field worldwide. For clarity, clause (b) above does not include the rights to make, have made, sell or offer for sale Licensed Products in the Field in the Territory.

4.3 Sublicenses; Subcontracting. Unless otherwise restricted by any Existing License or New License, the rights granted to Aventis and its Affiliates under the Regeneron Intellectual

Property and Regeneron Trademarks are sublicensable with the prior written consent of Regeneron, which consent shall not be unreasonably withheld, conditioned or delayed outside of the United States; *provided, however*, that nothing shall prevent Aventis from sublicensing its rights to a Distributor to sell or offer to sell the Licensed Product in the Field in the Territory (other than the United States). For the avoidance of doubt, Regeneron may withhold such consent if Regeneron reasonably determines such sublicense would reduce its financial return from this Agreement in the applicable country. Aventis shall remain responsible and liable for the compliance by its Affiliates and its and their permitted sublicensees and Distributors with applicable terms and obligations set forth herein, including payment under this Agreement and the Supply Agreement with respect to Net Sales of Licensed Products in the Field by such Affiliates, sublicensees or Distributors. Aventis agrees that any sublicense granted pursuant to this ARTICLE 4 or ARTICLE 11 shall be consistent with, and expressly subject to, the covenants, terms and conditions set forth in this Agreement. Promptly after entering into any such sublicense, or any amendment or modification thereto, Aventis will provide a true and correct copy thereof to Regeneron. Aventis shall also have the right to contract with one or more Third Parties to perform certain of its obligations under the Plans if specifically contemplated therein, *provided* that Aventis shall remain responsible and liable for the acts and omissions of such Third Party service providers and such Third Parties undertake in writing obligations of confidentiality and non-use of New Information and/or Party Information that are substantially the same as those undertaken by Aventis under this Agreement. In the event of a breach by a sublicensee, Distributor or a Third Party contractor of any sublicense or subcontract granted or awarded hereunder by Aventis which has or is reasonably likely to have a material adverse effect on Regeneron or the Regeneron Intellectual Property or Regeneron Trademarks, then Regeneron may cause Aventis to exercise, and Aventis will promptly exercise, any termination rights it may have under the sublicense or subcontract with such sublicensee, Distributor or Third Party contractor. All sublicenses and subcontracts granted under this Agreement will terminate upon termination or expiration of this Agreement.

4.4 No Implied License. Except as expressly provided herein, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patents, Know-How, Party Information or the other Party's interest in the Joint Intellectual Property either expressly or by implication, estoppel or otherwise.

4.5 Technology Transfer. To the extent reasonably necessary for each Party to exercise its rights and perform its obligations under this Agreement with respect to the other Party's intellectual property, and from time to time during the Term, each Party shall provide to the other Party one (1) copy of books and records embodying such Party's applicable intellectual property, to the extent such books and records may exist or be created in the ordinary course of business.

4.6 Certain Newly Created Intellectual Property. In addition to the other licenses granted under this ARTICLE 4 and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party hereby grants to the other Party and its Affiliates the perpetual, royalty-free, paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses through multiple tiers, to use and practice for any

and all purposes: (a) all intellectual property (including, without limitation, Know-How, Patents and Patent applications and copyrights), other than Excluded Rights, discovered, invented, authored or otherwise created by or on behalf of such Party, its Affiliates or its or their sublicensees or Distributors (other than by the other Party or its Affiliates) after January 31, 2006 directly in connection with the performance of the research activities and/or clinical development activities under this Agreement, in each case, as included in Co-Development Plans (as defined in this Agreement prior to the Amendment Execution Date) or the Development Plan, and (b) the Patents and Know-How identified on Schedule 2 (which were discovered or otherwise created by Regeneron (either solely or with Third Party collaborators) directly in connection with the performance of the Co-Development Plans (as defined in this Agreement prior to the Amendment Execution Date) prior to January 31, 2006). As used above, the term “Excluded Rights” shall mean any Patents or Know-How claiming or covering the composition (including any formulation) of a VEGF Product, including, without limitation, a VEGF Trap Product. For the avoidance of doubt, nothing in this Section 4.6 shall be construed to grant either Party any license to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by or on behalf of such Party, its Affiliates or its or their sublicensees or Distributors (other than by the other Party or its Affiliates) outside of the approved research activities and/or clinical development activities under this Agreement, in each case, as included in Co-Development Plans (as defined in this Agreement prior to the Amendment Execution Date) or the Development Plan.

## **ARTICLE 5 DEVELOPMENT ACTIVITIES**

5.1 Development of Licensed Products. After the Amendment Effective Date, subject to the terms of this Agreement, as between the Parties, Aventis shall be solely responsible for all aspects of the Development of the Licensed Products in the Field in the Territory, including all costs and expenses related thereto, and shall conduct such Development in accordance with the Development Plan. Without limitation of Section 5.2, Aventis shall (a) use Commercially Reasonable Efforts to Develop, and obtain and maintain Approvals for, the Licensed Products in the Field in the Territory and carry out the Development activities assigned to it in the Development Plan, and (b) conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices and export and import control Laws. Any dispute under this Section 5.1 regarding whether or not Aventis has used Commercially Reasonable Efforts to Develop, and obtain and maintain Approvals for, the Licensed Products in the Field in the Territory and carry out the Development activities assigned to it in the Development Plan shall be subject to resolution in accordance with Section 10.2.

5.2 Development Plan. Aventis shall provide an initial plan for the Development of the Licensed Product in the Field in the Territory to Regeneron (the “Development Plan”), after considering Regeneron’s comments in good faith, within thirty (30) days after the Amendment Execution Date. The Parties shall review the Development Plan at least every six (6) months for the purpose of considering appropriate amendments thereto. In the event that Aventis desires to amend the Development Plan in the Field, Aventis shall provide the terms of such proposed amendment to Regeneron in a timely manner prior to implementation of such amendment for Regeneron’s review and comment. Aventis shall consider Regeneron’s comments in good faith.

Aventis shall have final decision-making authority regarding any such proposed amendment to the Development Plan in the Field, except with respect to amendments to the Development Plan relating to the conduct of pre-clinical or non-clinical activities with respect to the Development of the Licensed Products in the Field in the Territory, which amendments shall require the prior written consent of Regeneron (not to be unreasonably withheld or delayed). Notwithstanding the foregoing, Aventis shall not undertake any Development activities or amend the Development Plan in any way that may be reasonably expected to have an adverse impact on an Excluded Ocular VEGF Product anywhere in the world. In the event that (a) Regeneron believes in good faith that the Development Plan or any such proposed amendment thereto does not constitute Commercially Reasonable Efforts or otherwise satisfy Aventis' obligations under this Agreement with respect to a Licensed Product or (b) Regeneron reasonably believes in good faith that any Development activities or any proposed amendment to the Development Plan may be reasonably expected to have an adverse impact on an Excluded Ocular VEGF Product anywhere in the world, Regeneron shall have the right to refer any such dispute described in clause (a) for resolution in accordance with Section 10.2, and any such dispute described in clause (b) for resolution in accordance with Section 10.3 as promptly as possible, and Aventis shall refrain from pursuing the disputed activities or amending the Development Plan during the pendency of any such dispute. Regeneron shall have no obligation with respect to the Development of (and, except as otherwise provided in this Agreement, no right to Develop) Licensed Products in the Field in the Territory, including under the Development Plan, unless and until the Parties agree in writing as to such Development activities and the associated Regeneron Costs, in which case Regeneron shall be reimbursed for such Regeneron Costs pursuant to Section 9.5. The Parties agree that any activities performed by or on behalf of Regeneron to satisfy the requirements of Regulatory Authorities in connection with the manufacture of Licensed Products shall be deemed to have been authorized by Aventis.

5.3 Additional Development Activities. At Aventis's request, Regeneron shall continue to provide support with regard to VEGF Trap anti-drug antibody dosing in biological samples measurement subject to Aventis prior approval of the associated costs, which costs shall be Regeneron Costs and shall be reimbursed by Aventis pursuant to Section 9.5; other Development activities may be performed by Regeneron as discussed and agreed between the Parties.

5.4 Development Reports. Within forty-five (45) days after the end of each six (6)-month period during which Aventis is conducting Development activities hereunder, Aventis shall provide to Regeneron a written report (in electronic form) summarizing the material activities undertaken by Aventis during such six (6)-month period in connection with the Development Plan, its Development activities in process and the future activities it expects to initiate during the following twelve (12)-month period. Each such report shall contain sufficient detail to enable Regeneron to assess Aventis' compliance with its obligations set forth in Section 5.1, including: (i) Aventis', or its Affiliates' or its or their sublicensees' or Distributors' activities with respect to achieving Approvals of Licensed Products in the Territory, (ii) clinical study results and results of other Development activities, (iii) communications with Regulatory Authorities with respect to Licensed Products, and (iv) pharmacovigilance activities. Upon

reasonable request by Regeneron, the Parties shall meet to review the information provided in such Development reports.

5.5 Development Records. Aventis shall, and shall cause its Affiliates and its and their sublicensees and Distributors to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (a) be appropriate for patent and regulatory purposes, (b) be in compliance with applicable Law, (c) properly reflect all work done and results achieved in the performance of its Development activities hereunder, (d) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (e) be retained by Aventis for at least three (3) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by applicable Law. Either Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Section 5.5; *provided, however*, that the other Party shall maintain such records and information disclosed therein in confidence in accordance with ARTICLE 16.

5.6 Obligations of The Parties And Their Affiliates. The Parties shall cause their respective Executive Officers to take the actions and make the decisions provided under this Agreement to be taken and made by such Executive Officers in the manner and within the applicable time periods provided under this Agreement and consistent with the purpose of optimizing the commercial potential of and financial returns from the Licensed Products consistent with other products at a similar stage in development or product life and of similar market potential and without regard to any other pharmaceutical product in development or being commercialized or sold by or through a Party or any of its Affiliates (the "Collaboration Purpose"). To the extent a Party performs any of its obligations under this Agreement or under an Ancillary Agreement through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement or any Ancillary Agreement which restricts or prohibits a Party from taking any specified action.

## **ARTICLE 6 COMMERCIALIZATION**

6.1 Commercialization of Licensed Products. As between the Parties, Aventis shall be solely responsible for the Commercialization of the Licensed Products in the Field in the Territory at Aventis' sole cost and expense. Without limitation of Section 6.2, Aventis shall use Commercially Reasonable Efforts to Commercialize the Licensed Products throughout the Territory. Any dispute under this Section 6.1 regarding whether or not Aventis has used Commercially Reasonable Efforts to Commercialize the Licensed Products throughout the Territory shall be subject to resolution in accordance with Section 10.2.

6.2 Commercialization Plan. The Commercialization of the Licensed Products in the Field in the Territory shall be conducted pursuant to a comprehensive, two-year plan (the "Commercialization Plan"). Aventis shall provide the initial Commercialization Plan within

thirty (30) days after the Amendment Execution Date. At all times, the Commercialization Plan shall include, with respect to the Territory generally and each Major Market Country in the Territory: (i) the general strategies for the promoting, marketing and distributing the Licensed Products; (ii) pre-launch Commercialization activities and the expected date of launch; (iii) the nature of promotional activities anticipated; (iv) any proposed use of Distributors by Aventis, its Affiliates or sublicensees; (v) non-binding summary sales forecasts for the Licensed Products; (vi) plans regarding distribution and supply chain management; (vii) reimbursement and pricing information; (viii) plans for any Non-Approval Trials; and (ix) sales force resourcing. At least every six (6) months, Aventis shall update Regeneron on changes to market conditions impacting or reasonably expected to impact the Commercialization of one or more Licensed Products in the Field in the Territory generally or in a Major Market Country in the Territory and shall propose amendments to the Commercialization Plan to address any such changes and to otherwise satisfy Aventis' diligence obligations set forth in Section 6.1. Aventis shall perform the Commercialization activities under the Commercialization Plan and shall use Commercially Reasonable Efforts to do so in accordance with the timelines and so as to achieve the objectives set forth in the Commercialization Plan. Upon reasonable request by Regeneron, the Parties shall meet to discuss the Commercialization Plan.

6.3 Commercialization Reports. Within forty-five (45) days after the end of each six (6)-month period, Aventis shall provide to Regeneron, in electronic form, with detailed written reports of such Commercialization activities it has performed, or caused to be performed, since the preceding report and the future activities it expects to initiate during the following six (6)-month period in the Major Market Countries. Each such report shall contain sufficient detail to enable Regeneron to assess Aventis' compliance with its obligations set forth in Sections 6.1, 6.2 or 6.7, including, in each case: (i) sales force size and allocation; (ii) the number and position of details in the applicable period; (iii) the nature of promotional activities and Licensed Product sampling activities; (iv) market and sales promotional programs; (v) the conduct of advertising, public relations and other promotional programs, including professional symposia and speaker and peer-to-peer activity programs used in the Commercialization of such Licensed Product; (vi) Net Sales for such Licensed Product in the Territory; and (vii) any Non-Approval Trials. Upon reasonable request by Regeneron, the Parties shall meet to review the information provided in such Commercialization reports.

6.4 Commercialization Records. Aventis shall maintain complete and accurate books and records pertaining to Commercialization of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be in compliance with applicable Law and properly reflect all work done and results achieved in the performance of its Commercialization activities. Such records related to a Contract Year shall be retained by Aventis for the longer of (i) the period of time required by Aventis' internal records retention policy, (ii) the period of time required by applicable Law or (iii) two (2) years following the end of such Contract Year. Regeneron shall have the right (at its cost) during normal business hours and upon reasonable notice to inspect such books and records pertaining to the two (2) immediately preceding Contract Years; *provided*, that the books and records related to a Contract Year shall not be subjected to such inspection more than one (1) time unless a material discrepancy or an inconsistency with applicable Law is found; *provided further*, that Regeneron

shall maintain such records and information disclosed therein in confidence accordance with ARTICLE 16.

6.5 Booking of Sales and Licensed Product Distribution . Aventis (or its local Affiliate) shall invoice and book, and appropriately record, all sales by it or its Affiliate of the Licensed Products in the Territory. Aventis (or its local Affiliate) shall also be responsible for the distribution of the Licensed Products in the Field in the Territory and for paying Medicaid and other governmental rebates that are due and owing with respect to the Licensed Products distributed by Aventis, its Affiliates or its or their sublicensees or Distributors in the Territory.

6.6 [\*\*\*\*].

6.7 Restrictions on Sales Outside the Field. Aventis shall not, and shall not permit any of its Affiliates or any of its and their Relevant Licensees, to, distribute, market, promote, offer for sale or sell the Licensed Products, or any [\*\*\*\*] Product, directly or indirectly (a) to any Person for use outside the Field or (b) to any Person in the Field that Aventis or any of its Affiliates or any of its or their Relevant Licensees knows or has reason to know (i) is likely to distribute, market, promote, offer for sale or sell any Licensed Product or any [\*\*\*\*] Product for use outside the Field or assist another Person to do so (including any pharmacy, physician, hospital or other entity that is engaged in any compounding activities related to the Licensed Products or [\*\*\*\*] Products), or (ii) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product or [\*\*\*\*] Product for use outside the Field or assisted another Person to do so. If Aventis or any of its Affiliates receives or becomes aware of the receipt by a Relevant Licensee of any orders for any Licensed Product or [\*\*\*\*] Product for use outside the Field, such Person shall refer such orders to Regeneron. Aventis shall cause its Affiliates and its and their Relevant Licensees to notify Regeneron of any receipt of any orders for any Licensed Product or [\*\*\*\*] Product for use outside the Field. For the avoidance of doubt, any development, manufacture or commercialization of any [\*\*\*\*] Product by Aventis or any of its Affiliates or any of its and their Relevant Licensees shall be pursuant to and in strict accordance with Section 6.11(c). Without limiting the provisions of Section 6.3, Aventis and its Affiliates shall provide, and shall cause its and their Relevant Licensees to provide, to Regeneron all necessary information to enable Regeneron to assess Aventis' compliance with its obligations set forth in this Section 6.7. For the purposes of this Section 6.7, "Relevant Licensee" shall mean any (i) Third Party to whom Aventis or any of its Affiliates have granted a license or sublicense under rights to the Licensed Products or any [\*\*\*\*] Product in the Territory; or (ii) Distributor or any Third Party acting as a distributor for Aventis or any of its Affiliates with regard to the Licensed Products or any [\*\*\*\*] Product in the Territory.

6.8 Inventory Management. Aventis shall use Commercially Reasonable Efforts to manage, or cause to be managed, Licensed Product inventory on hand at wholesalers and other Distributors or sublicensees (or Affiliates) so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.9 Medical and Consumer Inquiries. Aventis shall have responsibility for responding to medical questions or inquiries from members of the medical and paramedical professions and

consumers regarding Licensed Products in the Field in the Territory. Regeneron shall refer all such questions about Licensed Products in the Field that it receives to Aventis.

6.10 Market Exclusivity Extensions. Aventis shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) Aventis has the exclusive legal right, whether by means of a Patent or through other rights granted by a Governmental Authority in such country, to market, price and sell a Licensed Product in such country, and (b) no generic equivalent of a Licensed Product is marketed in such country. Notwithstanding anything to contrary contained herein, Aventis shall not be required to extend the period of time available for market exclusivity described in the immediately preceding sentence in a given country if (i) Regeneron is supplying Formulated Bulk Product under the Supply Agreement and (ii) the amounts of Formulated Bulk Licensed Product supplied by Regeneron would be insufficient to meet the Commercial Supply Requirements of Licensed Product if such extension of market exclusivity was obtained; provided, that Aventis notify Regeneron at least thirty (30) days prior to any relevant deadline or filing date and provide it the right and opportunity to assume control over such matters and Aventis shall provide any such assistance in connection therewith as Regeneron may reasonably request.

6.11 Non-Compete; Activities Outside of the Agreement.

(a) Non-Compete. During the Term, neither Aventis nor its Affiliates or its or their sublicensees under this Agreement shall, directly or indirectly, either alone or through any Third Parties, develop, manufacture for use or sale in any part of the Territory, or commercialize any VEGF Products in the Territory except for the Licensed Products in the Field pursuant to this Agreement. In the event that (i) Regeneron terminates this Agreement for any reason or (ii) Aventis terminates this Agreement for any reason other than pursuant to Section 19.3 or Section 19.5, [\*\*\*\*], neither Aventis nor its Affiliates or its or their sublicensees under this Agreement shall, directly or indirectly, develop, manufacture or commercialize any VEGF Products in any part of the Territory. Aventis shall not be considered in breach of this Section 6.11(a) solely by reason of the acquisition by Aventis of a Person with a VEGF Product if prior to the closing of such acquisition, Aventis commits in writing to Regeneron that, promptly following the closing of such acquisition, it will divest itself of the offending rights and/or activity, and Aventis uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, Aventis ceases all development, manufacturing and/or commercialization, as applicable, of the offending VEGF Product(s).

(b) Certain Development Activities Outside of Agreement.

(i) Notwithstanding anything in this Section 6.11(b) or Section 6.11(a) to the contrary, Aventis and/or its Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical trial, initiated, sponsored and/or conducted by any Third Party, in each of the foregoing cases, with respect to the combination of Aventis' (or its Affiliate's) product, including, but not limited to, Eloxatin® (Oxaliplatin) and Taxotere®

(Docetaxel), together with any Third Party VEGF Product that has been granted a Marketing Approval for at least one indication in the applicable country, including, but not limited to Avastin® (bevacizumab) (in the United States and any other country where bevacizumab has been granted a Marketing Approval), in any oncology indication.

(ii) Notwithstanding Section 6.11(b)(i), in any indication for which a Licensed Product Developed under this Agreement has been granted a Marketing Approval in an applicable country, Aventis must give preference to such Licensed Product over a Third Party VEGF Product in clinical trials of a VEGF Product for use in combination with Aventis' (or its Affiliate's) product in the same indication to be studied in the intended clinical trial with the Third Party VEGF Product.

(iii) For any combination study with a Third Party VEGF Product covered by Section 6.11(b)(i) commencing after January 7, 2005, Aventis shall notify Regeneron prior to initiating such trial, such notice to include a brief synopsis of the protocol and a description of Aventis' (or its Affiliate's) role(s) and responsibilities in connection with the study. Further, for any combination study with a Third Party VEGF Product covered by Section 6.11(b)(i), Aventis shall promptly provide Regeneron with available results of such combination study, unless such disclosure is prohibited by law or contract.

(iv) Aventis and/or its Affiliates shall be entitled to use data from clinical trials permitted by this Section (b)6.11(b) to promote the combination of Aventis' product together with such Third Party VEGF Product. For the avoidance of doubt, Aventis and its respective Affiliates shall use or disclose Party Information of Regeneron or any of its Affiliates and New Information in connection with any of the activities described in this Section 6.11(b) only in accordance with the confidentiality and non-use provisions of ARTICLE 16.

(v) Notwithstanding anything in this Section 6.11(b) or Section 6.11(a) to the contrary, Aventis may initiate an Aventis or its Affiliate's sponsored pivotal clinical trial in an indication which combines Aventis' (or its Affiliate's) product and a Third Party VEGF Product if, such combination trial for Approval of Aventis' (or its Affiliates) product is required in writing by a Regulatory Authority, and, prior to the commencement of any such clinical trial, Aventis provides Regeneron with a copy of such written notification, a writing of the commencement of such clinical trial, and a brief synopsis of the protocol, including the expected commencement and completion dates.

(c) Certain Permitted Activities Outside Agreement. Notwithstanding anything in Section 6.11(a) to the contrary, Aventis (or its Affiliates) may develop and manufacture for use or sale solely by Aventis (or its Affiliates) and may have made by a Third Party for use or sale solely by Aventis (or its Affiliates) in any part of the Territory in the Field a [\*\*\*\*] Product outside the scope of this Agreement, but may only sell the [\*\*\*\*] Product so manufactured in any part of the Territory in compliance with the provisions of the immediately following sentence. Further, notwithstanding anything in Section 6.11(a) to the contrary, if Aventis terminates this Agreement with respect to a country (or the entire Territory) pursuant to Section 19.2, Aventis (or its Affiliates) may commercialize a [\*\*\*\*] Product outside the scope of this Agreement, in such country (or in the entire Territory if the entire Agreement is terminated) in

the Field after the first (1st) anniversary of the effective date of such termination with respect to such country (or the entire Territory). For the avoidance of doubt, neither Aventis nor its Affiliates nor its or their sublicensees may develop or commercialize a [\*\*\*\*] Product in the Excluded Ocular Field or manufacture a [\*\*\*\*] Product for use or sale in the Excluded Ocular Field.

(d) During the Term, neither Regeneron nor its Affiliates or its or their sublicensees under this Agreement shall, directly or indirectly, either alone or through any Third Parties, manufacture for sale in any part of the Territory or commercialize any VEGF Trap Products in the Territory except for the Excluded Ocular VEGF Products in the Excluded Ocular Field.

6.12 Post Marketing Clinical Trials. Subject to the provision of this Agreement, Aventis shall use Commercially Reasonable Efforts to comply with any Clinical Trial obligations with respect to registration Approval with respect to any Licensed Product in any country in the Territory, imposed by applicable Law or pursuant to the Approvals or otherwise required by a Regulatory Authority.

## **ARTICLE 7 REGULATORY AFFAIRS**

7.1 Ownership of Approvals and Registration Filings. Aventis shall own all Approvals and Registration Filings with respect to the Licensed Products in the Territory and shall have the rights and obligations set forth in Sections 7.2 to 7.8 (inclusive) with respect thereto. Except to the extent prohibited by applicable Law, Regeneron hereby assigns the Approvals and Registration Filings listed on Schedule 5 to Aventis or its designated Affiliate (the "Assigned Regeneron Regulatory Documentation").

### 7.2 Rights of Reference.

(a) Aventis and its Affiliates and licensees shall have, and Regeneron and its Affiliates hereby grant to Aventis and its Affiliates and licensees, the right to reference (with the right to grant further rights of reference pursuant to Section 4.3) all regulatory documentation (including all registration filings and approvals) Controlled by Regeneron (or its Affiliates) that relate to any Excluded Ocular VEGF Product as necessary to make, have made, import, use, sell and offer for sale the Licensed Products in the Field in the Territory. Promptly upon the request of Aventis, Regeneron or its Affiliate shall submit a letter of authorization to FDA or the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any Excluded Ocular VEGF Product regulatory documentation (including all registration filings and approvals) to be incorporated by reference in such Licensed Product regulatory filings.

(b) Regeneron and its Affiliates and licensees shall have, and Aventis and its Affiliates hereby grant to Regeneron and its Affiliates and licensees, the right to reference (with the right to grant further rights of reference through multiple tiers) the BLA(s), IND(s), and any Registration Filings and/or Approvals Controlled by Aventis (or its Affiliates) that relate to any Licensed Product as necessary to make, have made, import, use, sell and offer for sale the VEGF Products worldwide outside the Field in the Territory and VEGF Products (other than Licensed

Products) and other products for use with Licensed Products in the Field in the Territory. Promptly upon the request of Regeneron, Aventis or its Affiliates shall submit a letter of authorization to FDA or the applicable Regulatory Authority (and take such actions or make such other filings) in order to permit any Licensed Product IND, BLA, Registration Filing and/or Approval to be incorporated by reference in such VEGF Product or other product regulatory filings.

7.3 Regulatory Coordination and Assistance. Subject to the provisions of this ARTICLE 7, Aventis shall be solely responsible for overseeing, monitoring and coordinating all regulatory strategy and actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the Licensed Product in the Field in the Territory; *provided* that it shall adhere to the obligations in this ARTICLE 7. Notwithstanding the foregoing, and without limiting any of Regeneron's other rights under this Agreement, Regeneron shall be permitted to communicate with Regulatory Authorities with regard to the manufacture of Formulated Bulk Licensed Product at Regeneron under the Supply Agreement in response to direct inquiry from such Regulatory Authorities. The Parties will coordinate with regard to such communications.

(a) Both Parties will cooperate with each other to develop and follow specific procedures to be agreed upon to coordinate the exchange of necessary regulatory information from Licensed Products Developed and Commercialized by or on behalf of Aventis under this Agreement and Excluded Ocular VEGF Products developed and commercialized by Regeneron and its licensees. For the purpose of clarity, such regulatory information shall be limited to necessary regulatory information that could have a material impact on the manufacture, development or commercialization of the Licensed Products Developed and Commercialized by or on behalf of Aventis under this Agreement and Excluded Ocular VEGF Products developed and commercialized by Regeneron and its licensees.

(b) Regeneron agrees to promptly disclose to Aventis all relevant information related to Excluded Ocular VEGF Products developed and commercialized by Regeneron and its licensees that could have a material impact on the manufacture, development or commercialization of the Licensed Products. Aventis agrees to promptly disclose to Regeneron all relevant information related to Licensed Products Developed and Commercialized by or on behalf of Aventis under this Agreement that could have a material impact on the manufacture, development or commercialization of the Licensed Products or the Excluded Ocular VEGF Products. By way of example, categories of information that may have a material impact on the manufacture, development or commercialization of such products could include information having implications on safety; clinical; commercial; regulatory filings or CMC, including CMC issues arising during production or quality control of the Licensed Compound or EYLEA Drug Substance or in interactions with Regulatory Authorities regarding CMC issues relevant to both the Licensed Compound or EYLEA Drug Substance or on any CMC issues relevant to Formulated Bulk Licensed Product.

(c) With regard to Licensed Products Developed and Commercialized by or on behalf of Aventis under this Agreement, Regeneron shall not respond to or initiate any

communications, including verbal communications, with Regulatory Authorities or Governmental Authorities; *provided, however*, that the foregoing shall not apply with respect to any direct inquiry from Regulatory Authorities or Governmental Authorities regarding Licensed Products manufactured by Regeneron or its Affiliates. With regard to Excluded Ocular VEGF Products developed and commercialized by Regeneron and its licensees, Aventis shall not respond to or initiate any communications, including verbal communications, with Regulatory Authorities or Governmental Authorities.

(d) The Parties agree to discuss and, if practicable, coordinate with each other regarding any proposed change controls for any Licensed Compound manufactured or supplied under the Supply Agreement that will have a material impact on any Regulatory Filing for any Licensed Product; *provided, however*, that Regeneron will consider in good faith any comments provided by Sanofi; *provided, further*, that Regeneron will have final decision-making authority with respect to all change controls.

(e) The Parties shall work together cooperatively to develop a strategy with respect to regulatory and chemistry, manufacturing and controls issues common to both the Licensed Compound and the EYLEA Drug Substance. Notwithstanding the foregoing, in the event that a Regulatory Authority or Governmental Authority requests an immediate response from a Party regarding the Licensed Compound or from Regeneron regarding the EYLEA Drug Substance and such request relates to regulatory and chemistry, manufacturing and controls issues common to both the Licensed Compound and the EYLEA Drug Substance, such Party shall use Commercially Reasonable Efforts to consult with the other Party in advance of responding to such Regulatory Authority or Governmental Authority, but shall not be required to delay a response to such request.

(f) (i) Aventis shall notify Regeneron if any data regarding Licensed Products generated under this Agreement is submitted to Regulatory Authorities or Governmental Authorities in support of the Licensed Products to the extent Aventis determines that such data may reasonably be expected to have an adverse impact on Excluded Ocular VEGF Products. In the event that Aventis' regulatory strategy pertaining to such data may reasonably be expected to have an adverse impact on Regeneron's or its (sub)licensees' regulatory strategy used to support Excluded Ocular VEGF Products, Regeneron and Aventis shall discuss and agree to the proposed regulatory strategy pertaining to such data in advance of Aventis' (or its Affiliates' or licensees') communication with Regulatory Authorities or Governmental Authorities regarding such data. (ii) Regeneron shall notify Aventis if any data regarding Excluded Ocular Products generated outside of this Agreement is submitted to Regulatory Authorities or Governmental Authorities in support of the Excluded Ocular VEGF Products to the extent Regeneron determines that such data may reasonably be expected to have an adverse impact on Licensed Products. In the event that Regeneron's regulatory strategy pertaining to such data may reasonably be expected to have an adverse impact on Aventis' or its (sub)licensees' regulatory strategy used to support Licensed Products, Regeneron and Aventis shall discuss and coordinate with each other regarding the proposed regulatory strategy pertaining to such data in advance of Regeneron's (or its Affiliates' or licensees') communication with Regulatory Authorities or Governmental Authorities regarding such data; *provided, however*, that Regeneron will consider in good faith any

comments provided by Sanofi; provided, further, that Regeneron will have final decision-making authority with respect to all such regulatory strategies and the final content and position of any such communication with Regulatory Authorities and Governmental Authorities. Notwithstanding the foregoing, in the event Regeneron is contractually bound to a third party to maintain confidentiality of any such data referred to in the foregoing sentence, Regeneron shall use commercially reasonable efforts to obtain a waiver of confidentiality in order to provide such data to Aventis in a timely manner.

(g) (i) Aventis shall use Commercially Reasonable Efforts to provide to Regeneron within twenty-four (24) hours after receipt by Aventis (or Aventis' receipt from its Affiliates or licensees) from any Regulatory Authorities or Governmental Authorities any such information for the Licensed Products that it determines in good faith is materially relevant to the interests of the Excluded Ocular VEGF Products, including but not limited to development, regulatory communications and filings, safety, labeling, manufacturing or product quality for the Excluded Ocular VEGF Products, or any notice or results of inspections or manufacturing issues relevant to a VEGF Trap. Regeneron and Aventis shall discuss and agree on the response to be communicated to Regulatory Authorities or Governmental Authorities in the Major Market Countries regarding such information and Aventis shall provide a copy of the response submitted to such Regulatory Authorities or Governmental Authorities within twenty-four (24) hours of submission by Aventis (or Aventis' receipt of such a submission from a licensee). (ii) Regeneron shall use Commercially Reasonable Efforts to provide to Aventis within twenty-four (24) hours after receipt by Regeneron (or Regeneron's receipt from its' Affiliates or licensees) from any Regulatory Authorities or Governmental Authorities any such information for the Excluded Ocular VEGF Products that it determines in good faith is materially relevant to the interests of the Licensed Products, including but not limited to Development, regulatory communications and filings, safety, labeling, manufacturing or product quality for Licensed Products, or any notice or results of inspections or manufacturing issues relevant to Excluded Ocular Products. Regeneron and Aventis shall discuss and agree on the response to be communicated to Regulatory Authorities or Governmental Authorities regarding such information and Regeneron shall provide a copy of the response submitted to such Regulatory Authorities or Governmental Authorities within twenty-four (24) hours of submission by Regeneron (or Regeneron's receipt of such a submission from a licensee). Notwithstanding the foregoing, in the event Regeneron is contractually bound to a third party to maintain confidentiality regarding any such information referred to in this Section 7.3(g)(ii), Regeneron shall use commercially reasonable efforts to obtain a waiver of confidentiality in order to provide such information to Aventis in a timely manner.

(h) For purposes of clarification, subject to the provisions of this Section 7.3, Aventis and its licensees will have the sole right to determine the final content and position of any communication with Regulatory Authorities and Governmental Authorities with regard to Licensed Products in the Field in the Territory, *provided* that Aventis makes a good faith determination that such communication is not reasonably expected to have an adverse impact on the development and commercialization of Excluded Ocular VEGF Products in the Territory.

(i) To the extent that EYLEA Drug Substance uses Formulated Bulk Licensed Product, and Regeneron (i) decides to undertake a modification of EYLEA Drug Substance for the Excluded Ocular VEGF Product and (ii) the modification will have a material impact on the regulatory filings of the Licensed Product in the Field, Regeneron shall notify Aventis thereof and the Parties shall discuss the regulatory strategy for such EYLEA Drug Substance to the extent relating to such modification as follows:

- (x) in the Major Market Countries, (A) the Parties shall discuss the regulatory briefing strategy for background materials or submissions related to EYLEA Drug Substance at least ten (10) days prior to submission to Regulatory Authorities or Governmental Authorities, (B) Regeneron shall provide to Aventis a copy of such briefing materials no later than five (5) days prior to submission to a Regulatory Authority or Governmental Authority, (C) Aventis shall provide any comments to such briefing materials no later than forty-eight (48) hours following Regeneron's provision of such briefing materials, which comments shall be considered in good faith by Regeneron, and (D) Regeneron shall provide to Aventis a copy of the final documents; and
- (y) in the non-Major Market Countries, Regeneron shall notify Aventis within seventy-two (72) hours after Regeneron's submission (or Regeneron's receipt of such a submission from a licensee) of any background materials or submissions related to EYLEA Drug Substance to any Regulatory Authority or a Governmental Authority.

Regeneron shall consider Aventis' comments in good faith. Notwithstanding the foregoing, should a Regulatory Authority or Governmental Authority request an immediate response from Regeneron regarding Formulated Bulk Licensed Product, Regeneron shall use Commercially Reasonable Efforts to consult with Aventis in advance of a response, but Regeneron will not be required to delay a response to such request.

7.4 Pharmacovigilance and Safety Data Exchange. Without limiting the provisions of Section 7.5, the Parties will cooperate with each other to develop and follow specific procedures to be agreed upon and memorialized in a Safety Data Exchange Agreement to coordinate the exchange of necessary safety and pharmacovigilance information from Licensed Products Developed and Commercialized by or on behalf of Aventis under this Agreement and Excluded Ocular VEGF Products developed and commercialized by Regeneron and its licensees to ensure prompt communication of such notifications and compliance with reporting obligations to Regulatory Authorities.

7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will immediately provide to the other Party), the Party in receipt of the observations will prepare any appropriate

responses that concern a Licensed Product, provided that the other Party shall have the right to review and comment on such responses, except to the extent such responses contain information for which the Party in receipt of the observation owes an obligation of confidentiality to a Third Party, and such Party shall consider in good faith the comments made by such other Party. In the event that the Parties disagree concerning the form or content of a response, the Party that received the observations shall decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within twenty-four (24) hours of receipt of notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities being used or proposed to be used for the manufacture of Licensed Products.

7.6 Recalls and Other Corrective Actions. Aventis shall notify Regeneron promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Aventis shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Field in the Territory; *provided*, that prior to any implementation of such a recall, market suspension or market withdrawal, Aventis shall consult with Regeneron and shall consider Regeneron's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Territory, as between the Parties, Aventis shall initiate such a recall, market suspension or market withdrawal in compliance with applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 7.6, as between the Parties, Aventis shall be solely responsible for the execution thereof. Notwithstanding the provisions of this ARTICLE 7 or ARTICLE 16, Aventis shall provide Regeneron with copies of any proposed correspondence with Regulatory Authorities or any proposed public announcement, in each case, related to any voluntary or mandated recall of a Licensed Product in the Field in the Territory for Regeneron's review and comment prior to Aventis making or disclosing any such correspondence or public announcement. Aventis shall provide Regeneron with copies of any correspondence with Regulatory Authorities or any public announcement, in each case, related to any market suspension or market withdrawal of a Licensed Product in the Field in the Territory.

7.7 Cost of Recalls and Other Corrective Actions. Except as otherwise provided in ARTICLE 17 , Aventis shall be solely responsible for all costs of a recall, market withdrawal or other corrective action with respect to any Licensed Product in the Field in the Territory.

7.8 Licensed Product Labeling. Aventis shall use Commercially Reasonable Efforts to include language in approved labeling for Licensed Products in the Field in the Territory stating that the product is not intended for local administration to the eye.

## **ARTICLE 8 MANUFACTURING AND SUPPLY**

8.1 Supply Agreement. Simultaneously with execution of this Agreement, the Parties (or their Affiliates) are amending and restating that certain commercial supply agreement, dated June 10, 2013, by and between Regeneron and Sanofi Winthrop Industrie, under which Aventis or its Affiliate shall procure Formulated Bulk Licensed Products from Regeneron or its Affiliates (the “Supply Agreement”). Regeneron or its Affiliates shall supply Formulated Bulk Licensed Product to Aventis (or its Affiliate) under the Supply Agreement pursuant to the terms thereof until the expiration or termination of the Supply Agreement.

8.2 Aventis Manufacturing and Supply Obligations.

(a) As between the Parties, Aventis shall be solely responsible, at its sole cost and expense, for all activities related to finishing, packaging, and labeling of Finished Licensed Product in the Territory.

(b) Aventis shall use Commercially Reasonable Efforts to, at its election, either (a) [\*\*\*\*], or (b) otherwise [\*\*\*\*], for the manufacture of Formulated Bulk Licensed Product for the supply of Commercial Supply Requirements and Clinical Supply Requirements of Licensed Products in the Territory. Without limiting the foregoing, Regeneron shall, at Aventis’ sole cost and expense, use Commercially Reasonable Efforts to assist Aventis (or its Affiliate) to, as the case may be, [\*\*\*\*], or [\*\*\*\*] for the manufacture of Formulated Bulk Licensed Product in order to meet Aventis’ obligations under this Section 8.2.

(c) Aventis may otherwise elect to establish an alternative source, for the manufacture of Formulated Bulk Licensed Product for the supply of Commercial Supply Requirements and Clinical Supply Requirements of Licensed Products in the Territory (x) through one of its other existing manufacturing facilities, (y) by constructing and obtaining all required approvals and validations by Regulatory Authorities for a new manufacturing facility or (z) with Regeneron’s prior consent (which consent shall not be unreasonably withheld, conditioned or delayed), through a Third Party manufacturer other than [\*\*\*\*], in each case ((x), (y) and (z)), at Aventis’ own expense.

(d) All costs and expenses (including capital expenditures) required to provide additional manufacturing capacity pursuant to Sections 8.2(b) and 8.2(c), including without limitation the related start-up and validation activities and the transfer of the manufacturing process for the Licensed Products from Regeneron (or its Affiliates) to Aventis or a Third Party manufacturer, shall be paid solely by Aventis.

8.3 Funded Assets. Notwithstanding anything to the contrary in the Funded Assets MOU, the Parties acknowledge and agree that all title to the Funded Assets (as defined in the Funded Assets MOU) has transferred to Regeneron and Regeneron has no further obligations to Aventis or its Affiliates with respect to the Funded Assets under the Funded Assets MOU.

**ARTICLE 9  
PAYMENTS**

9.1 Payments. Aventis or SWI shall make payments to Regeneron or its Affiliates under this Agreement and the Supply Agreement pursuant to this ARTICLE 9.

9.2 Development Balance; Other Payment Obligations. Notwithstanding anything to the contrary in this Agreement or the Supply Agreement, the Development Balance due and owing by Regeneron to Aventis as of the Amendment Effective Date shall be extinguished and cancelled, without any further act of either Party and there shall be no further accrual of the Development Balance following the Amendment Effective Date. Without limiting the foregoing, nothing in this Agreement shall relieve either Party of any payment obligations arising prior to the Amendment Effective Date. From and after the Amendment Effective Date, Aventis shall be solely responsible for all costs and expenses associated with the Development and Commercialization of the Licensed Products in the Field in the Territory and Regeneron shall have no obligation to reimburse Aventis for any costs or expenses incurred by or on behalf of Aventis in connection with the Development and Commercialization of the Licensed Products in the Territory after the Amendment Effective Date.

9.3 Net Sales Report. Within twenty (20) days after the end of each Calendar Quarter, Aventis shall calculate and report to Regeneron the amount of Net Sales, that are attributable to the Licensed Product in each country in the Territory during such Calendar Quarter (including such amount expressed in local currency and as converted into U.S. Dollars in accordance with Section 9.9). Without limiting the generality of the foregoing, Aventis shall require its Affiliates and its and their sublicensees and Distributors to calculate and account for their Net Sales and to provide such reports with respect thereto, in sufficient detail and at such time so that Aventis can meet its obligations to Regeneron hereunder if such sales were made by Aventis.

9.4 Third Party Payment Amounts. Aventis shall be solely responsible for paying all Third Party Payment Amounts, or reimbursing Regeneron on a Calendar Quarter-by-Calendar Quarter basis pursuant to Section 9.8 for any Third Party Payment Amount made by Regeneron, in each case pursuant to the terms of this Section 9.4. Aventis shall, in addition to the Net Sales Report provided pursuant to Section 9.3, provide Regeneron within forty-five (45) days after the end of each Calendar Quarter with deductions taken to arrive at Net Sales and all other information necessary to satisfy Regeneron's obligations with respect to any Third Party Payment Amounts under any Existing License or New License to which Regeneron is a party. Notwithstanding the Genentech Settlement Letter, the Parties acknowledge and agree that Aventis shall be responsible for making, and shall make, all payments due under the Genentech Settlement Agreement directly to Genentech, Inc. (and not to Regeneron pursuant to this Section 9.4).

9.5 Regeneron Costs. Subject to Section 5.2, Aventis shall, on a Calendar Quarter-by-Calendar Quarter basis pursuant to Section 9.8, reimburse Regeneron for all of the Regeneron Costs incurred by Regeneron after the Amendment Effective Date; provided, however, that for any Regeneron Costs incurred by Regeneron for the benefit of both Licensed Product and any Excluded Ocular VEGF Product, Aventis shall only be required to reimburse [\*\*\*\*] of such Regeneron Costs. Regeneron shall provide Aventis all such information related to Regeneron Costs for a Calendar Quarter within forty-five (45) days after the end of each Calendar Quarter.

9.6 Profit Sharing Payment.

(a) The Parties acknowledge and agree that in order to ease the administrative and accounting burdens on the Parties under this Agreement and to provide for the commercial supply of Licensed Products, they have elected to forego the calculation of net profits from sale of Licensed Product and the sharing of net profits under this Agreement, and the associated reporting, reimbursement and reconciliation processes, and instead have agreed that Aventis or SWI shall make payments to Regeneron (or its Affiliate) under this Agreement and the Supply Agreement based on a simplified profit sharing arrangement calculated as a percentage of Net Sales, as set forth in this Section 9.6. Such payments are, in part, intended to reflect the value contributed by Regeneron with respect to its discovery of the VEGF Trap and the development and commercialization of the Licensed Products. For clarity, in the event that the Supply Agreement is terminated for any reason, Aventis shall continue to be obligated to make payments to Regeneron under this Section 9.6 in accordance with the terms hereof.

(b) Aventis shall pay to Regeneron, on a Calendar Quarter-by-Calendar Quarter basis pursuant to Section 9.8, a percentage of the aggregate Net Sales of all Licensed Products in the Field in the Territory during each Contract Year (each such quarterly payment, a “Profit Sharing Payment”), which percentage shall be based on the aggregate Net Sales of all Licensed Products in the Field in the Territory during such Contract Year as set forth in the chart below (the aggregate amount of such payment due with respect to Net Sales in a given Contract Year, the “Aggregate Profit Sharing Payment”).

<b>Aggregate Net Sales of Licensed Products in the Field in the Territory during each Contract Year</b>	<b>Percentage of Aggregate Net Sales</b>
Aggregate annual Net Sales of Licensed Products less US\$[****]	15%
Aggregate annual Net Sales of Licensed Products equal to or greater than US\$[****] but less than US\$ [****]	[****]
Aggregate annual Net Sales of Licensed Products equal to or greater than US\$[****] but less than US\$ [****]	[****]
Aggregate annual Net Sales of Licensed Products equal to or greater than US\$[****] but less than US\$ [****]	[****]
Aggregate annual Net Sales of Licensed Products equal to or greater than US\$[****]	30%

By way of example, if aggregate Net Sales of all Licensed Products in the Field in the Territory in a Contract Year are US\$ 600,000,000, the Aggregate Profit Sharing Payment in respect of such Contract Year shall be equal to [\*\*\*\*]% Net Sales of US\$ 600,000,000 (*i.e.*, US\$ [\*\*\*\*]), which example is described in greater detail in Schedule 10.

(c) The Profit Sharing Payment due in respect of a given Calendar Quarter shall be equal to (i) the amount of the Aggregate Profit Sharing Payment owed to Regeneron with respect to Net Sales in such Contract Year through the end of such Calendar Quarter

("Cumulative Net Sales"), less (ii) the amount of the Aggregate Profit Sharing Payment, if any, already paid to Regeneron with respect to Cumulative Net Sales in prior Calendar Quarters of such Contract Year.

9.7 Payments with respect to Batches under the Supply Agreement. Regeneron shall sell to SWI, and SWI shall purchase from Regeneron, during the Supply Term, the Product at the following price, payable as follows:

(a) Regeneron shall invoice SWI for the Estimated Fully Burdened Batch Price applicable to each Batch that was manufactured and shipped pursuant to a Firm Order under the Supply Agreement, and SWI shall pay such amount within forty-five (45) days after the date of such invoice. Beginning in the 2016 Contract Year, within forty-five (45) days after the end of each Calendar Quarter, Regeneron shall provide a good faith estimate of the Aggregate Actual Fully Burdened Manufacturing Cost for that Contract Year.

(b) With respect to Batches to be manufactured in the 2016 Contract Year and each Contract Year thereafter during the Supply Term, Regeneron shall provide in writing to SWI by [\*\*\*\*] Regeneron's good faith estimate of the Actual Fully Burdened Manufacturing Costs of any Batch to be manufactured in such Contract Year, which estimate shall be based on the Actual Fully Burdened Manufacturing Cost of prior years, current year-to-date manufacturing costs, the number of Batches expected to be manufactured in such Contract Year, and any other relevant factors (the "Estimated Fully Burdened Batch Price"). The Estimated Fully Burdened Batch Prices for the 2014 Contract Year and the 2015 Contract Year are set forth in Appendix 1.

(c) Beginning with Product manufactured in the 2016 Contract Year, clauses (i), (ii) and (iii) of this Section 9.7(c) shall apply:

(i) Within sixty (60) days after the end of each Contract Year during the Supply Term, Regeneron shall calculate and provide SWI with (A) (1) the total Actual Fully Burdened Manufacturing Cost for all quantities of Product manufactured during such Contract Year pursuant to a Firm Order, [\*\*\*\*], and the cost of any Batches that were [\*\*\*\*], and (2) amounts due to Regeneron in respect of quantities of Product in respect of a Firm Order which [\*\*\*\*] (the sum of (1) and (2) the "Aggregate Actual Fully Burdened Manufacturing Cost"), (B) the total amount of the payments based on the Estimated Fully Burdened Batch Price for such Contract Year that have been invoiced to SWI (the "Payment Total"), which shall equal the product of (x) the number of Batches that were manufactured during such Contract Year [\*\*\*\*] (the "Batch Number"), and (y) the Estimated Fully Burdened Batch Price for such Contract Year, and (C) the amount equal to the difference between the Aggregate Actual Fully Burdened Manufacturing Costs and the Payment Total (the "Reconciliation Amount"). In the event that, with respect to a Contract Year, the Aggregate Actual Fully Burdened Manufacturing Cost is greater than the Payment Total, then Regeneron shall invoice SWI for the Reconciliation Amount. In the event that, with respect to a Contract Year, the Payment Total is greater than the Aggregate Actual Fully Burdened Manufacturing Cost, then SWI shall invoice Regeneron for the Reconciliation Amount. Any invoice prepared pursuant to the foregoing two sentences will be prepared by the appropriate Party within ten (10) days of receipt by SWI of the report containing the Reconciliation Amount. The Party receiving an invoice pursuant to the foregoing three

sentences shall pay the Reconciliation Amount within thirty (30) days after the date of such invoice.

(ii) With regard to Batches manufactured in any given Contract Year within the Supply term, which [\*\*\*\*], Regeneron shall invoice SWI for their Actual Fully Burdened Manufacturing Cost and SWI shall pay such amount within forty-five (45) days after the date of such invoice.

(iii) For clarity, with respect to any Batches manufactured in a given Contract Year but shipped after the end of such Contract Year, Regeneron shall invoice SWI, in accordance with Section 9.7(a) and pursuant to Section 9.8, the amount of the Estimated Fully Burdened Batch Price in effect during the Contract Year in which such Batch was manufactured, regardless of whether a Reconciliation Payment was made by either Party under this Section 9.7(c). To the extent any Batches manufactured in a given Contract Year are shipped after [\*\*\*\*], (i) Regeneron shall invoice SWI for their Estimated Fully Burdened Manufacturing Cost, (ii) SWI shall pay such amount within forty-five (45) days after the date of such invoice and (iii) any Reconciliation Amount payable on such batches shall be carried forward to the reconciliation for the subsequent year and added to the Reconciliation Amount to be calculated for such year pursuant to Section 9.7(c)(i). For further clarity, in no event shall this Section 9.7(c) diminish Aventis's obligations to provide Firm Orders pursuant to Section 5.1 of the Supply Agreement.

9.8 Quarterly Invoicing and Payment. Following the end of each Calendar Quarter, within fifteen (15) days after receipt by Regeneron of the Net Sales Report from Aventis pursuant to Section 9.4, Regeneron shall invoice Aventis the following amounts due for such Calendar Quarter: (i) all Third Party Payment Amounts due in respect of such Calendar Quarter pursuant to Section 9.4, (ii) the amount of Regeneron Costs incurred by Regeneron in such Calendar Quarter which are due pursuant to Section 9.5, and (iii) the amount of the Profit Sharing Payment due with respect to such Calendar Quarter pursuant to Section 9.6 and in accordance with the form of calculation set forth on Schedule 10. Aventis shall pay the amount due to Regeneron pursuant to such invoice(s) within twenty five (25) days after receipt by Aventis of such invoice(s). For clarity, the receipt date shall be the date any invoice is electronically received by Aventis.

9.9 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to U.S. Dollars using the spot rates the average of the daily spot rates fixed by the European Central Bank from the last Business Day of the preceding month, as published on the website located on the following URL: <http://sdw.ecb.europa.eu/browseSelection.do?DATASET=0&sf1=4&FREQ=M&sf3=4&CURRENCY=USD&node=2018794>. In the event of a payment dispute under this ARTICLE 9, the disputing Party shall be required to pay all non-disputed amounts pursuant to the terms of ARTICLE 9 and may withhold the payment only of any disputed amounts and only during the pendency of any such dispute.

9.10 Late Payments . The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to one month London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted on Thomson Reuters Eikon (or any other source agreed to by the Parties) effective for the date on which the payment was due, [\*\*\*\*] (such sum being referred to as the “Default Interest Rate”).

9.11 Taxes. Any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder or the Ancillary Agreements, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; *provided, however*, that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

All amounts due under this ARTICLE 9 are exclusive of sales, use, goods and services, value added, excise, and other taxes, duties or charges of a similar nature imposed by any Governmental Authority, or other taxing authority. If any sales, use, goods and services, value added, excise, and other taxes, duties or charges of a similar nature will be chargeable with respect to payments made under this ARTICLE 9, Aventis shall pay to, or upon receipt of invoice from Regeneron, shall reimburse, Regeneron these in addition to the sums otherwise payable, at the rate in force at the due time for payment or such other time as is stipulated under the relevant legislation.

## **ARTICLE 10 DISPUTE RESOLUTION**

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party’s rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Legal Disputes. The Parties agree that, subject to Sections 10.4 and 16.4, they shall use all reasonable efforts to resolve any Legal Dispute arising under this Agreement by good faith negotiation and discussion. In the event that the Parties are unable to resolve any such Legal Dispute either Party may submit the Legal Dispute to the Executive Officers for resolution, specifying the nature of the Legal Dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred Legal Dispute within thirty (30) days of receiving such written notification. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve

any such Legal Dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise.

10.3 Escalation to Executive Officers. In the event of a dispute between the Parties with respect to any Development activities or any proposed amendment to the Development Plan pursuant to Section 5.2, either Party may, on written notice to the other Party, refer such dispute to the Executive Officers for a joint decision, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within thirty (30) days of receiving such written notification. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. In the event that the Executive Officers are unable during such thirty (30)-day period to resolve a dispute between the Parties with respect to whether or not any Development activities or any proposed amendment to the Development Plan may be reasonably expected to have an adverse impact on an Excluded Ocular VEGF Product anywhere in the world, Regeneron's Executive Officer shall have final decision-making authority. In the event that the Executive Officers are unable during such thirty (30)-day period to resolve a dispute between the Parties with respect to any Development activities or any proposed amendment to the Development Plan other than a dispute with respect to whether or not any Development activity or proposed amendment to the Development Plan may be reasonably expected to have an adverse impact on an Exclude Ocular VEGF Product anywhere in the world, Aventis' Executive Officer shall have the final decision-making authority.

10.4 No Waiver. Nothing in this ARTICLE 10 shall prohibit either Party from seeking immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions of the other.

## **ARTICLE 11 TRADEMARKS AND CORPORATE LOGOS**

11.1 Corporate Logos. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. As between the Parties, Aventis shall have the sole right to select one or more Product Trademarks (including back-up trademarks) for each Licensed Product for use with respect to such Licensed Product.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, (a) Regeneron (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s) for the Licensed Products, together with all associated trade dress, trade names, services marks, .us domain names and all associated social media identifiers and accounts for the Licensed Products and the Regeneron Licensed Product Domain Names, in the United States, and all goodwill related thereto (the "Regeneron Trademarks"), and (b) Aventis (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s) for the Licensed Products, together with all associated trade dress, trade names, services marks, gTLD and ccTLD (other than .us domain name) for the Licensed Products, in all countries in the Territory other than the United States and all goodwill related thereto (the "Aventis Trademarks").

11.4 Prosecution and Maintenance of Product Trademarks. Aventis will use Commercially Reasonable Efforts to register, and to prosecute and maintain any registration and registration application for, the Aventis Trademarks for the Licensed Products in all countries in the Territory other than the United States, and Aventis will use Commercially Reasonable Efforts to register, and to prosecute and maintain any registration and registration application for, the Regeneron Trademarks for the Licensed Products in Regeneron's name in the United States. Notwithstanding the foregoing, in the event Aventis elects not to register, or to prosecute or maintain any registration or registration application for, any Aventis Trademark or any Regeneron Trademark for the Licensed Products in the Territory, Regeneron shall have the right to do so on behalf of Aventis for use with the Licensed Products in the Field during the Term, subject to consultation and cooperation with Aventis. The Parties agree that Aventis shall be solely responsible for [\*\*\*\*] costs and expenses incurred in connection with the prosecution and maintenance of the Aventis Trademarks and the Regeneron Trademarks during the Term, except in the event that Regeneron elects to assume responsibility for the prosecution and maintenance of any Aventis Trademark or Regeneron Trademark, in which case Regeneron shall bear [\*\*\*\*] of all costs and expenses incurred in prosecuting and maintaining such Aventis Trademark or Regeneron Trademark.

11.5 License to the Licensed Product Trademarks. Regeneron hereby grants to Aventis a license to use the Regeneron Trademarks to manufacture, Develop and Commercialize the Licensed Products in the Territory pursuant to this Agreement and subject to the terms and conditions of this Agreement. Aventis' rights under this Section 11.5 may be sublicensed, but only to its Affiliates and permitted sublicensees and Distributors pursuant to the terms of Section 4.3 for the purposes of, and subject to the terms and conditions of, this Agreement. Except as provided in this Agreement, neither Party shall have rights in or to the other Party's Product Trademarks or the goodwill pertaining thereto. Aventis shall utilize the Regeneron Trademarks only on approved Promotional Materials or other approved product-related materials for the Licensed Products for the purposes contemplated herein. All use by Aventis or its Affiliates or permitted sublicensees or Distributors of the Regeneron Trademark(s) shall be in accordance with such quality standards and trademark usage guidelines established by Regeneron that it deems reasonably necessary to preserve its rights in, and the validity and enforceability of, the Regeneron Trademark(s), including any registration and registration application therefor, and the goodwill therein, and which Regeneron may modify and supplement from time to time upon written notice thereof to Aventis, and all goodwill generated through such use shall inure to the sole benefit of Regeneron for the purposes of trademark and trade name ownership, registration, enforcement and maintenance. Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademark, trade dress, service mark, trade name or domain name or social media identifier that is confusingly similar to, misleading or deceptive with respect to the other Party's Product Trademark(s) for the Licensed Products or take any action or do any act that endangers, damages, dilutes, destroys or similarly affects, in any material respect, the other Party's trademark or the value of the goodwill pertaining thereto or attack, dispute or contest the validity of or ownership of the other Party's Product Trademark(s) or any registrations or pending registration thereof. Aventis agrees that upon termination or expiration of the Term, it will discontinue forthwith all use of the Regeneron Trademark. Upon request by Aventis, Regeneron shall (or shall cause its Affiliates, as appropriate, to) execute such

documents as may reasonably be required for the purpose of recording with any Governmental Authority the license referred to above in this Section 11.5.

#### 11.6 Use of Corporate Names.

(a) Aventis shall not use Regeneron's or its Affiliates' corporate names or logos on any Promotional Materials related to the Licensed Products (including, without limitation, congress booths or Promotional Materials used or distributed in connection with the applicable Licensed Product) in the Field or otherwise in the Territory; *provided, however*, that Aventis shall (i) be permitted to identify Regeneron (or its Affiliate) as the manufacturer of the Licensed Products in any such materials to the extent required under any applicable Law and for so long as Regeneron or its Affiliate is supplying Licensed Products to Aventis or its Affiliates under the Supply Agreement and (ii) use Commercially Reasonable Efforts to include in any such materials the phrase "*ZALTRAP was developed in collaboration with Regeneron Pharmaceuticals, Inc.*" or similar language to the extent permitted under any applicable Law, in each case ((i) and (ii)), consistent with the provisions of Section 11.5.

(b) Accordingly, unless Regeneron has terminated this Agreement pursuant to Sections 19.3, 19.4, 19.5 or 19.6 or Aventis has terminated this Agreement pursuant to Section 19.2, Regeneron hereby grants to Aventis (and its Affiliates) a non-exclusive license, with the right to grant sublicenses in accordance with Section 4.3, to use Regeneron's corporate names or logos solely as provided in this Section 11.6 during the Term and thereafter for a maximum period of two (2) years solely to the extent necessary to exhaust the existing inventory of Licensed Product and such materials containing Regeneron's corporate names or logos. Without limiting the foregoing, Aventis shall not and shall not permit its Affiliates or its or their sublicensees or Distributors to, (m) use in their respective businesses, any trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of Regeneron's corporate names or logos, (n) take any action or do any act that endangers, damages, dilutes, destroys or similarly affects, in any material respect, Regeneron's corporate names or logos or the value of goodwill pertaining thereto, or (o) attack, dispute or contest the validity of or ownership of Regeneron's corporate names or logos anywhere in the Territory or any registrations or any pending registration thereof. Aventis agrees and shall cause its Affiliates and its and their sublicensees or Distributors, to conform (y) to the customary industry standards for the protection of the trademarks and to such trademark usage guidelines as Regeneron may furnish from time to time with respect to the use of Regeneron's corporate names or logos and (z) to adhere to and maintain the highest quality standards of Regeneron with respect to goods sold and services provided under Regeneron's corporate names or logos.

## **ARTICLE 12 NEWLY CREATED INVENTIONS**

### 12.1 Ownership of Newly Created Intellectual Property.

(a) Each Party shall exclusively own all right, title and interest in and to any and all intellectual property (including, without limitation, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement solely by or on behalf of such Party, its Affiliates or its or their sublicensees or Distributors

(other than by the other Party or its Affiliates) (“Sole Inventions”). Sole Inventions made solely by or on behalf of Aventis, its Affiliates or its or their sublicensees or Distributors (other than Regeneron and its Affiliates) are referred to herein as “Aventis Sole Inventions.” Sole Inventions made solely by or on behalf of Regeneron, its Affiliates or its or their sublicensees or Distributors (other than Aventis and its Affiliates) are referred to herein as “Regeneron Sole Inventions.” The Parties agree that nothing in this Agreement, and no use by a Party of the other Party’s intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party’s intellectual property, other than the license rights expressly granted hereunder.

(b) The Parties shall each own an equal, undivided interest in any and all intellectual property (including, without limitation, Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement during the Term jointly by or on behalf of Aventis, its Affiliates or its or their sublicensees or Distributors, on the one hand, and Regeneron, its Affiliates or its or their sublicensees or Distributors, on the other hand (“Joint Inventions”). Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their sublicensees and Distributors to so disclose, the conception, discovery, invention or reduction to practice of any Joint Invention.

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is an Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent applications) is an Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property vests in a Party, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign, and shall cause its Affiliates and its and their sublicensees and Distributors to so assign, to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party’s use of the Joint Inventions is governed by the terms and conditions of this Agreement, including the terms of ARTICLE 4, as follows: each Party’s interest in the Joint Inventions may be sublicensed, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party, provided that each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee’s written agreement to be bound by the terms of this Section 12.1(e) and the other terms of this Agreement that relate to the Joint Inventions; *provided, further*, that nothing in this ARTICLE 12 shall relieve a Party or its Affiliates of their

obligations under ARTICLE 16 with respect to New Information or confidential Party Information provided by or on behalf of the other Party or such other Party's Affiliates. Except as otherwise provided in this Agreement with respect to the Licensed Products, neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense, or other exploitation of the Joint Inventions. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

#### 12.2 Prosecution and Maintenance of Patents.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Regeneron Patent Rights throughout the Territory, and shall confer with and keep Aventis reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of the Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Aventis for review and comment a copy of a substantially completed draft of any priority Patent application at least thirty (30) days prior to the filing of any such priority Patent application by Regeneron and consider in good faith any comment; (ii) Regeneron shall notify Aventis prior to the filing of a Patent Application by Regeneron; (iii) Regeneron shall consult with Aventis following the filing of the priority Patent application in sufficient time to permit the Parties to mutually determine in which countries it shall file convention Patent applications; (iv) Regeneron shall provide Aventis promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) Regeneron shall provide Aventis a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Regeneron Patent Rights (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Patent or not filing or perfecting the filing of any Patent application in any country), with notice of such proposed action or inaction so that Aventis has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that Regeneron desires to abandon any Regeneron Patent Rights, Regeneron shall provide reasonable prior written notice to Aventis of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent Right with the applicable patent office) and Aventis shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent applications that are unpublished, Regeneron notifies Aventis that Regeneron would prefer to maintain the subject matter of such Patent application as a trade secret.

(b) Aventis shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Aventis Patent Rights throughout the Territory, and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Aventis shall have the following obligations with respect to the filing, prosecution and maintenance of the Aventis Patent Rights: (i) Aventis shall use Commercially Reasonable Efforts to provide to Regeneron for review and comment a copy of a substantially completed draft of

any priority Patent application at least thirty (30) days prior to the filing of any such priority Patent application by Aventis and consider in good faith any comment; (ii) Aventis shall notify Regeneron prior to the filing of a Patent application by Aventis; (iii) Aventis shall consult with Regeneron following the filing of the priority Patent application in sufficient time to permit the Parties to mutually determine in which countries it shall file convention Patent applications; (iv) Aventis shall provide Regeneron promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) Aventis shall provide Regeneron a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Aventis Patent Rights (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Patent or not filing or perfecting the filing of any Patent application in any country), with notice of such proposed action or inaction so that it has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that Aventis desires to abandon any Patent included in the Aventis Patent Rights, Aventis shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Aventis Patent Right with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Aventis' name, unless, with respect to any such Patent applications that are unpublished, Aventis notifies Regeneron that Aventis would prefer to maintain the subject matter of such Patent application as a trade secret.

(c) The Parties shall consult with each other regarding the filing, prosecution and maintenance of any Joint Patent Rights, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of the Joint Patent Rights: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide any priority Patent application at least thirty (30) days prior to the filing of any such priority Patent application by the Controlling Party and consider in good faith any comment from the non-Controlling Party; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party following the filing of the priority Patent application in sufficient time to permit the Parties to mutually determine in which countries it shall file convention Patent applications; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Joint Patent Rights (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent application, abandoning any Patent or not filing or perfecting the filing of any Patent application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing

obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent application within ninety (90) days of a written request by the non-Controlling Party to do so, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof (and will undertake such filings, prosecutions and maintenance in such Party's name). Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Joint Patent Rights on thirty (30) days' prior notice to the other Party, providing the non-Controlling Party the right to assume the prosecution or maintenance thereof in such non-Controlling Party's name and cost and expense.

(d) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Aventis Patent Rights, Regeneron Patent Rights and Joint Patent Rights, and any extensions thereof pursuant to Section 12.2(e)(e), shall be [\*\*\*\*], except to the extent that the prosecuting Party elects to abandon the applicable Aventis Patent Right, Regeneron Patent Right or Joint Patent Right, in which case the other Party shall bear [\*\*\*\*] of such Out-of-Pocket Costs if such other Party elects to assume responsibility for the prosecution and maintenance thereof as provided herein.

(e) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of the Regeneron Patent Rights, Aventis Patent Rights and Joint Patent Rights pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The Parties shall cooperate to determine for which of the Aventis Patent Rights, Regeneron Patent Rights and Joint Patent Rights to seek an extension of the term in the Territory.

### 12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, post-grant review, reissue or reexamination relating to Regeneron Patent Rights, Aventis Patent Rights, or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Decisions on whether to initiate such a proceeding and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Aventis, (ii) with respect to Aventis Patent Rights, by Aventis in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, post-grant review, reissue, or reexamination proceeding relating to the Regeneron Patent Rights, Aventis Patent Rights and/or Joint Patent Rights shall be [\*\*\*\*].

## ARTICLE 13

### INTELLECTUAL PROPERTY LITIGATION

#### 13.1 Enforcement of Patents and Product Trademarks.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement or unauthorized use, as applicable, of a Aventis Patent Right, a Regeneron Patent Right, a Joint Patent Right or any Product Trademark, in each case, by a Third Party's activities in the Territory (an "Infringement"), the Party that became aware of the Infringement shall promptly notify the other Party in writing and shall provide such other Party with all available evidence supporting such Infringement. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to such infringement.

(b) With respect to any Infringement, (i) Regeneron shall have the first right to bring and control any action or proceeding with respect to Infringement of any Regeneron Patent Right or of any Joint Patent Right that [\*\*\*\*], and (ii) Aventis shall have the first right to bring and control any action or proceeding with respect to Infringement of any Aventis Patent Right or Joint Patent Right other than a Joint Patent Right that [\*\*\*\*] (the Party with the first right being referred to as the "Lead Litigation Party"); *provided, however*, that the Parties shall ensure that there is proper communication and coordination of activities between the Parties. If the Lead Litigation Party fails to bring any such action or proceeding with respect to Infringement of the applicable Patent by a Third Party within sixty (60) days following notice of the alleged infringement (or such other period of time as may be required by applicable Law), the non-Lead Litigation Party shall have the right to bring and control any such action at its own expense by providing written notice to the other Party (the Party who controls the litigation to be referred to as the "Litigation Party"). The non-Litigation Party will provide reasonable assistance to the Litigation Party in prosecuting any action, and if required by Law, will join in the action. Although the Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party.

The non-Litigation Party shall have the right to (and, if required by Law, will) join in any litigation using counsel of its choice at its sole discretion and expense, subject to Section 13.1(c). The amount of any recovery from any such Infringement action shall be (i) retained [\*\*\*\*] and (ii) [\*\*\*\*], *provided* that any such recoveries shall be first allocated to [\*\*\*\*]. Notwithstanding the foregoing, any recoveries for lost sales or lost profits of a product for any Infringement hereunder shall be (A) with respect [\*\*\*\*] and (B) with respect to [\*\*\*\*].

(c) All Out-of-Pocket Costs (except for the expenses of the non-Litigation Party's counsel, if any) incurred in connection with any Infringement litigation under Section 13.1(b) shall be (i) borne [\*\*\*\*], (ii) borne [\*\*\*\*], (iii) [\*\*\*\*], and (iv) to the extent not otherwise covered in clauses (i) - (iii), borne [\*\*\*\*].

(d) For the avoidance of doubt, neither Party will enter into any settlement of any Infringement suit referenced in this Section 13.1 involving Licensed Products that materially adversely affects the other Party's rights or obligations with respect to the applicable Licensed Product (with respect to Regeneron as the settling party) or the VEGF Products (with respect to Aventis as the settling party), as applicable in the Territory without the other Party's prior written consent.

13.2 Patent Marking. Aventis shall comply with the patent marking statutes in each county in which a Licensed Product is made, offered for sale, sold or imported by such Party, its Affiliates and/or its or their sublicensees or Distributors.

### 13.3 Third-Party Infringement Claims.

(a) If either Party or its Affiliates becomes aware of a claim or assertion that the manufacture, Development or Commercialization of any Licensed Product in the Field infringes or otherwise violates the intellectual property rights of any Third Party in the Territory such Party shall promptly notify the other Party in writing of this claim or assertion. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement.

(b) The Parties shall cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, with respect to material court filings and the defense and/or settlement of any such claim; *provided, however*, that each Party shall have the right to defend and control the defense of any such action naming it as a defendant at its sole cost and expense, using counsel of its own choice; *provided further* that any counterclaim or defense alleging Infringement (or infringement) shall be governed by Section 13.1. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party alleging that the manufacture, Development or Commercialization of any Licensed Product in the Field infringes or otherwise violates the intellectual property rights of such Third Party in the Territory.

(c) Unless otherwise agreed by the Parties, each Party shall bear its own Out-of-Pocket Costs and internal costs (except for the expenses of the non-controlling Party's

cooperation pursuant to Section 13.3(b), if only one Party defends a claim) incurred in connection with any litigation under this Section 13.3.

(d) For the avoidance of doubt, neither Party will enter into any settlement of any suit involving Licensed Products that materially adversely affects the other Party's rights or obligations with respect to the applicable Licensed Product (with respect to Regeneron as the settling party) or the VEGF Products (with respect to Aventis as the settling party), as applicable in the Territory without the other Party's prior written consent.

#### 13.4 Invalidity or Unenforceability Defenses or Actions.

(a) In the event that a Third Party asserts, as a defense or as a counterclaim in any Infringement action (or infringement action) under Section 13.1, that any Regeneron Patent Rights, Aventis Patent Rights or Joint Patent Rights are invalid or unenforceable, then the Party first becoming aware of such claim shall promptly give written notice to the other Party. Subject to the assistance and coordination provisions described in Section 13.1(b), the Litigation Party shall have the final decision-making authority on responding to such defense or defending against such counterclaim (as applicable), including the right to settle or otherwise compromise such claim, in consultation with the non-Litigation Party.

(b) If a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party, that any Regeneron Patent Rights, Aventis Patent Rights or Joint Patent Rights are invalid or unenforceable, then the Party first becoming aware of such action or claim shall promptly give written notice to the other Party. The Party having the final decision-making authority on controlling the defense of such action or claim, including settlement negotiations and terms, will be (i) with respect to Regeneron Patent Rights, Regeneron in consultation with Aventis, (ii) with respect to Aventis Patent Rights, Aventis in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, the Parties jointly. Any such Party controlling the defense against any such action or claim shall use legal counsel mutually agreeable by the Parties, and the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim.

(c) All Out-of-Pocket Costs incurred in connection with responding to or defending against any action or claim that any Regeneron Patent Rights, Aventis Patent Rights or Joint Patent Rights are invalid or unenforceable pursuant to this Section 13.4 shall be borne in the same manner as set forth in Section 13.1(c) with respect to the allocation of costs for Infringement litigation.

(d) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.4 that materially adversely affects the other Party's rights or obligations with respect to Licensed Products (with respect to Regeneron as the settling party) or the VEGF Products (with respect to Aventis as the settling party), as applicable in the

Territory, including admitting the invalidity or unenforceability of any Regeneron Patent Rights, Aventis Patent Rights, or Joint Patent Rights, without the other Party's prior written consent.

## ARTICLE 14

### BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement or the Supply Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement or the Supply Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement or the Supply Agreement with, and be advised as to the same by, its and their officers and independent accountants.

#### 14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its costs), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any calendar year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement or the Supply Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided under this Agreement or the Supply Agreement; *provided* that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of receipt thereof. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to the dispute resolution procedures set forth in Section 10.2. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement or the Supply Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing Party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement or the Supply Agreement, and shall be subject to the confidentiality provisions contained in ARTICLE 16.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be

contested pursuant to Section 14.2(b) above, the Party (or its Affiliate) owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party (or its Affiliate) entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 14.2.

14.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement or the Supply Agreement shall be determined in accordance with GAAP or IAS/IFRS as generally and consistently applied.

## **ARTICLE 15 REPRESENTATIONS AND WARRANTIES**

15.1 Due Organization, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Amendment Execution Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under ARTICLE 4 hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Amendment Execution Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any governmental entity or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY VEGF PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT

**ARTICLE 16**  
**CONFIDENTIALITY**

16.1 Confidential Information. Each of Aventis and Regeneron acknowledges (subject to Section 16.2 and ARTICLE 19) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement is confidential and proprietary to such other Party or its respective Affiliates. Furthermore, each of Aventis and Regeneron acknowledges (subject to the further provisions of this ARTICLE 16) that all New Information is confidential and proprietary to both Parties (and both Parties shall be deemed to be the receiving Party with respect thereto). During the Term and for a period of ten (10) years thereafter, each of Aventis and Regeneron shall, and shall cause its officers, directors, employees and agents to, maintain in confidence and not disclose to any Third Party or not use the Party Information of the other Party (or its Affiliates) and all New Information, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement.

16.2 Exclusions. Notwithstanding anything provided above, the confidentiality and non-use restrictions provided in this ARTICLE 16 shall not apply to Party Information or New Information that was or is (and such information shall not be considered confidential or proprietary under this Agreement):

(a) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving party provided such information;

(b) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party; *provided, however*, that this exception shall not apply with respect to New Information;

(c) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; or

(d) similar in nature to the purported Party Information or New Information but has been independently created outside of this Agreement, as evidenced by written or electronic documentation, without any aid application or use of the Party Information or New Information.

16.3 Permitted Disclosures and Uses.

(a) Each Party may use or disclose Party Information of the other Party and New Information to the extent that such use or disclosure is:

(i) necessary or useful to file, prosecute, enforce or defend Patents or Patent applications for which the Party has the right to assume filing, prosecution, enforcement, defense or maintenance pursuant to this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law;

(ii) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded) or court order to be disclosed, *provided* that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information, and *provided further* that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information that is required by a Governmental Authority, applicable Law or court order to be disclosed;

(iii) used to enforce the terms of this Agreement or any Ancillary Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information; or

(iv) to the Regulatory Authorities as required in connection with obtaining or maintaining any application of a Licensed Product in the Field in the Territory pursuant to the terms of this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

(b) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information or Party Information of Aventis, in each case, related to Excluded Ocular VEGF Products and VEGF Products (including the making or use thereof):

(i) in connection with Regeneron's discovery, development, manufacture or commercialization of VEGF Products (other than a Licensed Product in the Field) in the Territory, including, without limitation, to existing or potential distributors, (sub)licensees, Affiliates or collaboration partners or otherwise in connection with the performance of its obligations or exercise of Regeneron's rights as contemplated by this Agreement; or

(ii) to the Regulatory Authorities as required in connection with obtaining or maintaining any application of a VEGF Product (other than a Licensed Product in the Field) in the Territory; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law.

(c) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any Party) relating to such tax treatment or tax structure, *provided, however*, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws.

16.4 Injunctive Relief. Each Party acknowledges that damages resulting from breach of this ARTICLE 16 would be an inadequate remedy and that, notwithstanding the provisions of ARTICLE 10, in the event of any such disclosure or use or any indication of an intent to disclose or use Party Information or New Information, the Party (or its Affiliates) owning such Party Information or New Information shall be entitled to seek, by way of private litigation, injunctive relief, whether preliminary or permanent, specific performance and other equitable relief, including an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity and reasonable attorneys' fees. In any such action for equitable relief in a court of competent jurisdiction, both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy.

16.5 Publication of New Information. During the Term, if either Aventis or Regeneron (the "Publishing Party") desires to disclose any New Information or Party Information of the other Party that relates to any Licensed Product in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information or such Party Information of the other Party prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary (a) to preserve the New Information or such other Party Information or (b) to enable the Parties to obtain patent protection if either Party deems it necessary), and the Publishing Party shall not unreasonably reject such comments and, if requested by the other Party, shall delay or prevent such disclosure or publication as reasonably proposed by such other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent application(s) or application(s) for a certificate of invention on the information involved.

16.6 Other Publications. During the Term, in the event that Aventis or Regeneron desires to issue any other press releases or public announcements concerning this Agreement or any Ancillary Agreement or any other activities contemplated thereunder, in each case, to the extent not otherwise addressed in Section 16.5, except as prohibited by a Governmental Authority or applicable Law, such Party agrees to provide to the other Party a copy of any public announcement, as soon as reasonably practicable (which, except under extraordinary circumstances, shall be at least five (5) Business Days) prior to its scheduled release; *provided*,

however, that, without prior submission to the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement or any Ancillary Agreement or any activities contemplated thereunder which information was included in a press release or public announcement which was previously approved by the other Party as part of a press release or other public disclosure concerning this Agreement or which contains only non-material factual (non-financial) information regarding this Agreement (e.g., that the Agreement remains in effect). Except as otherwise required by applicable Law, the Party whose press release has been reviewed shall remove any information the reviewing Party reasonably deems to be inappropriate for disclosure. In connection with any press release or other written public announcement issued by Aventis pursuant to this Section 16.6, Aventis shall use Commercially Reasonable Efforts to include in any such press release or public announcement the phrase “ZALTRAP was developed in collaboration with Regeneron Pharmaceuticals, Inc.” or similar language to the extent permitted under any applicable Law, consistent with the provisions of Section 11.5. Except as required by Law, or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this ARTICLE 16 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse at least equivalent in scope to those included herein. In furtherance of the foregoing provisions of this Section 16.6, each Party shall give the other Party a reasonable opportunity to review all filings of this Agreement and all filings describing the terms of this Agreement with any Governmental Authority, including without limitation the United States Securities and Exchange Commission, prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including without limitation the provisions of this Agreement for which confidential treatment should be sought.

## **ARTICLE 17**

### **INDEMNITY**

#### 17.1 Indemnity and Insurance.

(a) Aventis will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, (sub)licensees, distributors and agents (“Regeneron Indemnitees”) from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys’ fees and costs (collectively, “Damages”), arising from a Third Party’s claim, action, suit, judgment or settlement (a “Third Party Claim”) against a Regeneron Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Aventis or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, sublicensees, Distributors, representatives or other persons or entities working on their behalf) in the performance of this Agreement, including, without limitation, in connection with its Development, Commercialization, or manufacture of any Licensed Product;

(ii) material breach by Aventis (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Aventis would be a material breach by Aventis) of the terms of, or the representations and warranties made by it in, this Agreement or any applicable Ancillary Agreement to which it is a party; or

(iii) the exploitation of the Licensed Products, including any actions or omissions by Aventis or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, sublicensees, Distributors, representatives or other persons or entities working on their behalf) in connection therewith, except in each case ((i), (ii) and (iii), to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, sublicensees, distributors, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of the Supply Agreement.

(b) Regeneron will defend, indemnify and hold harmless Aventis, its Affiliates and its and their respective officers, directors, employees, sublicensees, Distributors and agents ("Aventis Indemnitees") from and against all Damages arising from a Third Party Claim against a Aventis Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, sublicensees, distributors, representatives or other persons or entities working on their behalf), including, without limitation, in connection with the development or commercialization of any Licensed Product; *provided, however*, that Regeneron's indemnification obligations with respect to the manufacture of Licensed Products shall be governed by the terms of the Supply Agreement; or

(ii) material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of, or the representations and warranties made by it in, this Agreement (other than ARTICLE 8, which shall be governed by and subject to the limitations set forth in the Supply Agreement), except in each case ((i) and (ii), to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Aventis or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, sublicensees, Distributors, representatives or other persons or entities working on their behalf) in the performance of this Agreement.

(c) Aventis will use Commercially Reasonable Efforts to procure and maintain during the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law in countries where the project is conducted, commercial general liability and product liability insurance in an amount not less than Ten Million Dollars (\$10,000,000) per occurrence and in the annual aggregate. Such

insurance shall insure against liability arising from this Agreement on the part of Aventis and any of its Affiliates, due to injury, disability or death of any person or persons, or property damage.

#### 17.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this ARTICLE 17 (an “Indemnified Party”) shall notify the Party potentially responsible for such indemnification (the “Indemnifying Party”) within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; *provided, however*, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.

(i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party’s responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; *provided, however*, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days’ prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; *provided, however*, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(iii) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 17.2, the Indemnified Party shall and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this ARTICLE 17, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

## **ARTICLE 18 FORCE MAJEURE**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement or any Ancillary Agreement for failure or delay in fulfilling or performing any term of this Agreement or any Ancillary Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God (“Force Majeure”). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

## **ARTICLE 19 TERM AND TERMINATION**

### 19.1 Term/Expiration of Term.

(a) The “Term” of this Agreement shall commence on the Effective Date and end at such time as neither Aventis, nor any of its Affiliates or its or their sublicensees or Distributors, is Developing or Commercializing any Licensed Product in the Field anywhere in the Territory (and such cessation of Development and Commercialization activities is acknowledged by both Parties to be permanent), unless earlier terminated as provided hereafter.

(b) Upon expiration of the Term, except as set forth in this Agreement (including Sections 19.7 and 19.8), all licenses and rights granted by a Party to the other Party hereunder shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause. Aventis may terminate this Agreement (a) on a country-by-country basis for all Licensed Products in such country on [\*\*\*\*] prior written notice to Regeneron or (b) with respect to the entire Territory for all Licensed Products on [\*\*\*\*] prior written notice to Regeneron; *provided, however*, that any termination of this Agreement in five

(5) or more of the Original Major Market Countries shall be treated as a termination of this Agreement in its entirety under clause (b). Except as otherwise provided below in this Section 19.2, the Agreement shall continue in full force and effect through the notice period set forth above (the “Termination Notice Period”). During the Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Aventis hereunder (y) such licenses and rights granted to Aventis shall automatically terminate as of a date specified in such notice(s) (but not later than the Termination Notice Period) in the Terminated Territory and (z) Aventis will promptly take the actions required by Schedule 6 or Schedule 7, as applicable, and Regeneron will reasonably cooperate with Aventis (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron’s (or its nominee’s) expeditious assumption during the Termination Notice Period, with as little disruption as reasonably possible, of the continued Development and/or Commercialization of such Licensed Product(s) in the Terminated Territory.

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using diligent efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use diligent efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the second sentence of this Section 19.3 shall instead be thirty (30) days (and the immediately following parenthetical clause in such sentence shall not apply). For purposes of this Section 19.3, the term “material breach” shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from the Collaboration, taken as a whole.

19.4 Termination for Aventis’ Material Breach of the Supply Agreement. In the event that Regeneron (or its Affiliate) terminates the Supply Agreement for Aventis’ (or its Affiliate’s) material breach thereof, Regeneron shall have the right to terminate this Agreement in its entirety upon thirty (30) days’ prior written notice to Aventis.

19.5 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) the other Party proposes a written agreement of

composition or extension of its debts, or (c) the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) the other Party shall propose or be a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors.

19.6 Termination for Breach of Investor Agreement. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, upon written notice to Aventis, if any of the Standstill Parties (as defined in the Amended and Restated Investor Agreement, dated as of January 11, 2014 (the “Investor Agreement”), by and among Aventis, sanofi-aventis US LLC, Aventis, sanofi-aventis Amérique du Nord and Regeneron) shall have breached Section 4.1 of the Investor Agreement. For the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of a *de minimis* breach of Section 4.1(a) of the Investor Agreement or an inadvertent breach of Section 4.1(g) of the Investor Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 4.1 of the Investor Agreement.

19.7 Effect of Termination/Expiration.

(a) Upon termination of this Agreement in its entirety pursuant to Section 19.2(b), 19.3, 19.4, 19.5 or 19.6, the provisions of Schedule 6 shall apply, and except to the extent required by Aventis to fulfill its obligations pursuant to Schedule 6 (and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), (i) all licenses and rights granted by Regeneron to Aventis hereunder shall automatically terminate and revert to Regeneron, and (ii) the licenses from Aventis and its Affiliates to Regeneron referred to in Schedule 6 shall come into full force and effect.

(b) Upon termination of this Agreement with respect to a Terminated Territory pursuant to Section 19.2(a) (but not in the case of any termination of this Agreement in its entirety), the provisions of Schedule 7 shall apply with respect to the Terminated Territory, and except to the extent required by Aventis to fulfill its obligations pursuant to Schedule 7 (and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), (i) all licenses and rights granted by Regeneron to Aventis hereunder with respect to the Terminated Territory shall automatically terminate and revert to Regeneron, and (ii) the licenses from Aventis and its Affiliates to Regeneron referred to in Schedule 7 with respect to the Terminated Territory shall come into full force and effect. Without limiting the foregoing, in the event that Aventis terminates this Agreement with respect to a Terminated Territory pursuant to Section 19.2(a), Regeneron shall not take any action with respect to the Development and Commercialization of the Licensed Product(s) in the Field in the Terminated Territory that could reasonably be expected to have a materially adverse impact on

Aventis' continued Development and Commercialization of the Licensed Product(s) in the Field in the Territory.

(c) Without limiting Section 19.8, upon termination of this Agreement, the following provisions of this Agreement shall survive the termination of this Agreement and shall continue to be enforceable: ARTICLE 12 and ARTICLE 13, *provided* that, with respect to all the countries of the world in the case of termination under Section 19.7(a), and with respect to the Terminated Territory in the case of termination under Section 19.7(b), (i) Regeneron shall have the first right, but not the obligation, to enforce the Aventis Patent Rights in the territory to which such termination applies pursuant to Section 13.1(b); (ii) any costs and expenses incurred in connection with the prosecution and maintenance (including any interference, opposition or reexamination) of the Regeneron Patent Rights, Aventis Patent Rights or Joint Patent Rights in the territory to which such termination applies, or the defense of any claim that any of the foregoing are invalid or unenforceable (excluding the cost of any counsel employed by the non-controlling Party) shall be treated as follows: (1) with respect to the Regeneron Patent Rights and Aventis Patent Rights, the Party controlling the prosecution, maintenance or defense of such Regeneron Patent Rights or Aventis Patent Rights shall be responsible for such costs, except in the event that Regeneron elects to assume responsibility for the prosecution and maintenance of the Aventis Patent Rights pursuant to Section 12.2(b), in which case Regeneron shall be responsible for the costs incurred by Regeneron in connection therewith, and (2) with respect to the Joint Patent Rights, the Parties shall [\*\*\*\*]; and (iii) any costs and expenses incurred in connection with the enforcement (and any resulting recoveries) of the Regeneron Patent Rights, Aventis Patent Rights or Joint Patent Rights in the territory to which such termination applies shall be the responsibility of the enforcing Party and the enforcing Party shall retain all recoveries with respect thereto; *provided, however*, that notwithstanding anything to the contrary in this Section 19.7(c), any recoveries for lost sales or profits of a product from any Infringement action hereunder shall be paid solely to or retained solely by the Party that is selling (or has the right to sell) such product.

19.8 Survival of Obligations. Except as otherwise provided in this ARTICLE 19, Schedule 6 or Schedule 7, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate to the extent of such expiration or termination, and this Agreement shall cease to be of further force or effect to the extent of such expiration or termination, *provided* that notwithstanding any expiration or termination of this Agreement:

(a) neither Aventis nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, with respect to Aventis, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that in the case of termination of this Agreement pursuant to Section 19.2, without limitation of and subject to Aventis' continuing obligations under the provisions referred to in Section 19.2, Aventis' other obligations hereunder shall terminate prior to expiration of the Termination Notice Period if prior to such expiration Regeneron enters into a collaboration agreement of substantially similar scope as, and providing

for the assumption and performance by the counterparty thereto of the obligations of Aventis under, this Agreement;

(b) subject to the provisions of this ARTICLE 19 (including Schedule 6 and Schedule 7 to the extent applicable), the following obligations shall survive the expiration or termination of this Agreement and shall continue to be enforceable: Sections 4.6, 5.5, 6.4, 6.7, 6.10, 6.11, 7.2 (solely with respect to Regeneron and, insofar as necessary to fulfill its ongoing regulatory obligations, Aventis), 7.3(f) and (g) (solely with respect to Aventis' obligations with respect to Excluded Ocular VEGF Products), 7.4, 7.5, 7.6 (first sentence), 7.7, 8.3, 11.1, 11.3(a), 11.5 (penultimate sentence), 11.6, 15.3, 19.1, 19.2, 19.7 (including Schedule 6 and Schedule 7), 19.8 and ARTICLE 9, ARTICLE 12 and 13 (subject to Section 19.7(c)), ARTICLE 14, ARTICLE 17, and ARTICLE 20 to the extent applicable.

(c) such expiration or termination and this ARTICLE 19 shall be without prejudice to any rights or remedies a party may have for breach of this Agreement, including, without limitation, any breach of the provisions referred to in clause (b) above; and

(d) if this Agreement is terminated with respect to the Terminated Territory pursuant to Section 19.2(a) (but not in its entirety), then following such termination the foregoing provisions set forth in this Section 19.8 shall remain in effect with respect to the Terminated Territory (to the extent they would survive and apply in the event this Agreement expires or is terminated in its entirety) and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Territory and be of no further force and effect (and for the avoidance of doubt all provisions of this Agreement shall remain in effect with respect to all countries in the Territory other than the Terminated Territory).

## **ARTICLE 20 MISCELLANEOUS**

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 20.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver

shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 8 attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service, or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement together with the Ancillary Agreements to the extent referred to herein contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Aventis and Regeneron.

20.6 Headings. The descriptive headings of Articles and Sections are inserted solely for convenience of reference and are not intended as complete or accurate descriptions of the content of such Articles or Sections.

20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction (“Modified Clause”), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction, provided, further that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.6 above. The other Party shall promptly cooperate in such filing or

notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Aventis or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Aventis or (b) the prior written consent of Aventis in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party, *provided* that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) subject to Section 19.6, to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Aventis Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may perform its obligations hereunder through one or more of its Affiliates, although each Party shall nonetheless be responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

20.13 Third-Party Beneficiaries. Except as provided below in this Section 20.13, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, ARTICLE 17 is intended to benefit, and to be enforceable by, in addition to the Parties, the other Regeneron Indemnitees and Aventis Indemnitees as if they were parties hereto.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Aventis nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or

representative of a Party 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 approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Aventis, and Aventis' legal relationship under this Agreement to Regeneron, shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR AVENTIS BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD-PARTY CLAIM WHICH IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE 17.

20.16 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employees from the other Party involved in the manufacture, Development or Commercialization of any VEGF Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.17 Rejection of Agreement in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed under or pursuant to this Agreement, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101 (35A) of the Bankruptcy Code subject to the protections afforded the non-rejecting Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country. The Parties agree that this Agreement shall not be deemed terminated by virtue of any rejection by a Party or its receiver or trustee under applicable bankruptcy Laws unless the non-rejecting Party fails to exercise its rights under Section 365(n) (1)(B) of the U.S. Bankruptcy Code (or its foreign equivalents). For clarity, if the non-rejecting Party fails to exercise such rights or such rights are not available in a country outside the United States, this Agreement shall be deemed terminated. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous Laws in any other country or jurisdiction, if this Agreement is not terminated or deemed terminated, the Party hereto that is not the subject of such proceeding shall be entitled to a complete duplicate of (or

complete access to, as appropriate) all such intellectual property and all embodiments of such intellectual property, which, if not already in such Party's possession, shall be promptly delivered to it upon such Party's written request, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement.

#### 20.18 Construction.

(a) The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words "will" and "shall" shall have the same meaning and the use of the word "or" is used in the inclusive sense (and/or). The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with "without limitation" or "without limiting" throughout this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(b) The captions of this Agreement are for convenience or reference only and in no way define, describe, extend or limit the scope of intent of this Agreement or in the intent of any provision contained in this Agreement. Unless otherwise specified, (i) the references in this Agreement to any Article, Section, Schedule or Appendix means references to such Article, Section, Schedule or Appendix of this Agreement, (ii) references in any section to any clause are references to such clause of such section and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement and notification of such approval or consent is not delivered within the applicable time limit, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against any Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules and Appendices hereto, this Agreement shall prevail. In the event of any conflict between this Agreement and the Supply Agreement, this Agreement shall control.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, Aventis and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

SANOFI-AVENTIS US, LLC

By /s/ Robert DeBerardine  
Name: Robert DeBerardine  
Title: General Counsel, Sanofi North America

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray A. Goldberg  
Name: Murray A. Goldberg  
Title: Senior Vice President

*SIGNATURE PAGE TO LICENSE AGREEMENT*

SCHEDULE 1

Existing Licenses

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SCHEDULE 2

Certain Newly Created Intellectual Property

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SCHEDULE 5

Assigned Regeneron Regulatory Documentation

None

## SCHEDULE 6

### Transition Arrangements Following Termination in its Entirety.

1. Aventis shall promptly collect and return, and cause its Affiliates and its and their sublicensees and Distributors to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing Party Information or New Information directly relating to the Licensed Products, and shall immediately cease, and cause its Affiliates and its and their sublicensees and Distributors to cease, all further use of any such Party Information or New Information with respect to such Licensed Products. In addition, at Regeneron's request, Aventis shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, product samples, and Licensed Product inventory. Notwithstanding the foregoing in this Schedule 6, Aventis may retain copies of any Party Information or New information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes. Regeneron shall be entitled to use and disclose any such information (including any such Party Information and/or New Information) in connection with the manufacture, Development or Commercialization of Licensed Products.

2. Aventis shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and/or Commercialization of the Licensed Products. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following when, if and as requested by Regeneron:

(a) Aventis shall grant, and does hereby grant, to Regeneron a fully paid-up, royalty-free, exclusive license (which shall include the right to grant sublicenses through multiple tiers) from Aventis under the Aventis Patent Rights, Aventis Know-How, and Aventis' interest in the Joint Intellectual Property existing at the effective date of termination to Develop, make, have made, use, import, offer to sell and sell the VEGF Products inside and outside of the Field in the Territory.

(b) Aventis shall transfer and assign to Regeneron (or its nominee) all Approvals and regulatory filings (including Registration Filings) made or obtained by Aventis or its Affiliates or any of its or their sublicensees or Distributors to the extent specifically relating to the Licensed Products (other than Approvals for Aventis manufacturing facilities).

(c) Aventis shall assign and transfer to Regeneron (or its nominee) Aventis' entire right, title and interest in and to all Product Trademarks to the extent specifically relating to the Licensed Products and to any domain names containing such Product Trademarks; provided that nothing herein is intended to convey any rights in or to Aventis' corporate name and logos or any trade names of Aventis (other than the Product Trademarks).

(d) Aventis shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture,

Development or Commercialization of the Licensed Products in the Territory) of all information (including any Party Information and/or New Information)) in its possession or under its control to the extent directly relating to any Licensed Products, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Aventis, or such other format as may be reasonably requested by Regeneron.

(e) [\*\*\*\*\*].

(f) [\*\*\*\*\*].

(g) Without limitation of Aventis' other obligations under this Schedule 6, Aventis will take the actions required by subparagraph (g)(i) below to the extent it is responsible for supplying Commercial Supply Requirements of such Licensed Product in such country pursuant to ARTICLE 8

(i) Aventis will supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of finished and packaged Licensed Products at the same price, and on such other terms and conditions on which Aventis was supplying, or in the absence of termination, would have been required to supply such finished and packaged Licensed Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Aventis that it is able to manufacture or have manufactured Licensed Products on comparable financial terms.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development and Commercialization of the Licensed Products hereunder to Regeneron (or its sublicensee or third party designee) as soon as is reasonably possible.

4. For the avoidance of doubt, Regeneron shall not be required to provide Aventis any consideration in exchange for the licenses, transfers, assignments or other rights granted to it pursuant to the provisions of this Schedule 6; *provided, however*, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Aventis may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights; and *provided, further*, that if Aventis continues to manufacture the Licensed Products in such terminated country pursuant to paragraph (g) above, Regeneron shall purchase such products at the price, and on such other terms and conditions specified therein.

## SCHEDULE 7

### Transition Arrangements Following Termination in the Terminated Territory.

1. Aventis shall promptly collect and return, and cause its Affiliates and its and their sublicensees and Distributors to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing Party Information or New Information directly relating to the Licensed Products in the Terminated Territory, and shall immediately cease, and cause its Affiliates and its and their sublicensees and Distributors to cease, all further use of any such Party Information or New Information with respect to such Licensed Products in the Terminated Territory. In addition, at Regeneron's request, Aventis shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, product samples, and Licensed Product inventory relating to the Terminated Territory. Notwithstanding the foregoing in this Schedule 7, Aventis may retain copies of any Party Information or New information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes. Regeneron shall be entitled to use and disclose any such information (including any such Party Information and/or New Information) in connection with the manufacture, Development or Commercialization of Licensed Products.

2. Aventis shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and/or Commercialization of the Licensed Products in the Terminated Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following when, if and as requested by Regeneron:

(a) Aventis shall grant, and does hereby grant, to Regeneron a fully paid-up, royalty-free, exclusive license (which shall include the right to grant sublicenses through multiple tiers) from Aventis under the Aventis Patent Rights, Aventis Know-How, and Aventis' interest in the Joint Intellectual Property existing at the effective date of termination (i) to Develop, make, have made, use, import, offer to sell and sell the VEGF Products inside and outside of the Field in the Terminated Territory and (ii) to Develop, make, have made, use and import the VEGF Products inside the Field in the Territory solely in support of the Development and Commercialization of the VEGF Products in the Terminated Territory.

(b) Aventis shall transfer and assign to Regeneron (or its nominee) all Approvals and regulatory filings (including Registration Filings) in the Terminated Territory made or obtained by Aventis or its Affiliates or any of its or their sublicensees or Distributors to the extent specifically relating to the Licensed Products (other than Approvals for Aventis manufacturing facilities) in the Terminated Territory.

(c) Aventis shall assign and transfer to Regeneron (or its nominee) Aventis' entire right, title and interest in and to all Product Trademarks in the Terminated Territory to the extent specifically relating to the Licensed Products and to any domain names containing such Product Trademarks; *provided* that nothing herein is intended to convey any rights in or to

Aventis' corporate name and logos or any trade names of Aventis (other than the Product Trademarks in the Terminated Territory).

(d) Aventis shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture, Development or Commercialization of the Licensed Products in the Territory) of all information (including any Party Information and/or New Information)) in its possession or under its control to the extent directly relating to any Licensed Products in the Terminated Territory, including, without limitation, all information contained in the regulatory and/or safety databases with respect to such Terminated Territory, all in the format then currently maintained by Aventis, or such other format as may be reasonably requested by Regeneron.

(e) [\*\*\*\*].

(f) [\*\*\*\*].

(g) Aventis shall provide to Regeneron all necessary information and reasonable assistance in connection with Regeneron's submissions to (including Registration Filings) or communications with Regulatory Authorities regarding Licensed Products, the Licensed Compound or the EYLEA Drug Substance in the Terminated Territory.

(h) Without limitation of Aventis' other obligations under this Schedule 7, Aventis will take the actions required by subparagraph (h)(i) below to the extent it is responsible for supplying Commercial Supply Requirements of such Licensed Product in the Terminated Territory pursuant to ARTICLE 8.

(i) Aventis will supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of finished and packaged Licensed Products for the Terminated Territory at the same price, and on such other terms and conditions on which Aventis was supplying, or in the absence of termination, would have been required to supply such finished and packaged Licensed Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Aventis that it is able to manufacture or have manufactured Licensed Products on comparable financial terms.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development and Commercialization of the Licensed Products in the Terminated Territory hereunder to Regeneron (or its sublicensee or third party designee) as soon as is reasonably possible.

4. Aventis shall not, and shall not permit any of its Affiliates or any of its and their licensees, sublicensees or Distributors to, distribute, market, promote, offer for sale or sell the Licensed Products directly or indirectly (a) to any Person for use outside the Territory or (b) to any Person in the Territory that Aventis or any of its Affiliates or any of its or their licensees, sublicensees or Distributors knows or has reason to know (i) is likely to distribute, market, promote, offer for sale or sell any Licensed Product for use in the Terminated Territory or assist another Person to do so (including any pharmacy, physician, hospital or other entity that is

engaged in any compounding activities related to the Licensed Products), or (ii) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product for use in the Terminated Territory or assisted another Person to do so. If Aventis or any of its Affiliates receives or becomes aware of the receipt by a licensee, sublicensee or Distributor of any orders for any Licensed Product for use in the Terminated Territory, such Person shall refer such orders to Regeneron. Aventis shall cause its Affiliates and its and their licensees, sublicensees and Distributors to notify Regeneron of any receipt of any orders for any Licensed Product for use in the Terminated Territory.

5. Regeneron shall not, and shall not permit any of its Affiliates or any of its and their licensees, sublicensees or distributors to, distribute, market, promote, offer for sale or sell the Licensed Products directly or indirectly (a) to any Person for use in the Field outside the Terminated Territory or (b) to any Person in the Field in the Terminated Territory that Regeneron or any of its Affiliates or any of its or their licensees, sublicensees or Distributors knows or has reason to know (i) is likely to distribute, market, promote, offer for sale or sell any Licensed Product for use in the Field in the Territory or assist another Person to do so (including any pharmacy, physician, hospital or other entity that is engaged in any compounding activities related to the Licensed Products), or (ii) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product for use in the Field in the Territory or assisted another Person to do so. If Regeneron or any of its Affiliates receives or becomes aware of the receipt by a licensee, sublicensee or distributor of any orders for any Licensed Product for use in the Field in the Territory, such Person shall refer such orders to Aventis. Regeneron shall cause its Affiliates and its and their licensees, sublicensees and distributors to notify Aventis of any receipt of any orders for any Licensed Product for use in the Field in the Territory.

6. For the avoidance of doubt, Regeneron shall not be required to provide Aventis any consideration in exchange for the licenses, transfers, assignments or other rights granted to it pursuant to the provisions of this Schedule Z; *provided, however*, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Aventis may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights with respect to the Terminated Territory; and *provided, further*, that if Aventis continues to manufacture the Licensed Products in the Terminated Territory pursuant to paragraph (h) above, Regeneron shall purchase such products at the price, and on such other terms and conditions specified therein.

## SCHEDULE 8

### Notices

- (a) If to Aventis:  
sanofi-aventis U.S. LLC  
55 Corporate Drive  
Bridgewater, NJ 08807  
Attention: President

With a copy to: General Counsel

- (b) If to Regeneron:  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591 U.S.A.  
Attention: President  
Copy: General Counsel

SCHEDULE 9

Regeneron Licensed Product Domain Names

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SCHEDULE 10

Example of Profit Sharing Payment

An example of a calculation of profit sharing payments owed by Aventis to Regeneron for a Contract Year if aggregate sum of the Net Sales of all Licensed Products in the Field in the Territory in each Calendar Quarter of such Contract Year is \$US 600,000,000 would be as follows:

	Q1	Q2	Q3	Q4	Annual Total
<b>(A)</b> Quarterly Net Sales*	100	130	170	200	600
<b>(B)</b> Cumulative Net Sales by Quarter*	100	230	400	600	
<b>(C)</b> Applicable Percentage of Aggregate Net Sales, as set forth in Section 9.6(b)	[****]				
<b>(D) = ((B) x (C))</b> Aggregate Profit Sharing Payments Owned on Cumulative Net Sales for all Calendar Quarters to date in such Contract Year*	[****]				
<b>(E)</b> Portion of the Aggregate Profit Sharing Payments Paid in Prior Calendar Quarters of such Contract Year*	[****]				
<b>((D)-(E)) Profit Sharing Payment Due for Applicable Quarter*</b>	[****]				
<b>Total Profit Sharing Payment for the Contract Year*</b>					[****]

\*All amounts in \$US millions

SCHEDULE 11

ACTUAL FULLY BURDENED MANUFACTURING COST AND PERIOD COSTS

Capitalized terms used in this Schedule 11 that are not otherwise defined herein or in the Agreement shall have the meaning ascribed to them in the Supply Agreement.

1. Actual Fully Burdened Manufacturing Cost.

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2. Period Costs. “**Period Costs**” shall mean the following:

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3. Contract Manufacturers. With respect to any Actual Fully Burdened Manufacturing Costs paid to contract manufacturers or other Third Parties in connection with the manufacture of Product, [\*\*\*\*]. [\*\*\*\*]

APPENDIX 1

ESTIMATED FULLY BURDENED BATCH PRICE FOR PRODUCT MANUFACTURED IN 2014 AND 2015

2014 Estimated Fully Burdened Batch Price:    \$[\*\*\*\*]\*<sup>1</sup>  
2015 Estimated Fully Burdened Batch Price:    \$[\*\*\*\*]\*<sup>1</sup>

(1) [\*\*\*\*].

Date: February 27, 2015

To: Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591-6707

Attention: Dominick Agron  
VP and Treasurer  
777 Old Saw Mill River Road  
Tarrytown, NY 10591-6707

Facsimile: (914) 847-1555

From: Goldman, Sachs & Co.  
200 West Street  
New York, NY 10282-2198

Re: Third Amendment of the Warrant Transaction between Goldman, Sachs & Co. and Regeneron Pharmaceuticals, Inc.

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Dear Sir/Madam:

Goldman, Sachs & Co. (“**GS&Co.**”) and Regeneron Pharmaceuticals, Inc. (“**Issuer**”) are parties to a warrant transaction evidenced by the Master Terms and Conditions for Base Warrants Issued by Regeneron Pharmaceuticals, Inc. dated as of October 18, 2011, supplemented by the written confirmation dated as of October 18, 2011 (as amended prior to the date hereof, the “**Confirmation**”). Terms used herein but are not otherwise defined shall have meanings assigned to them in the Confirmation.

Upon the effectiveness of each daily Amendment as set forth in Paragraph 1 below, all references in the Confirmation to the “Number of Warrants” will be deemed to be to the Number of Warrants as amended hereby and all references in the Confirmation to the “Transaction” will be deemed to be to the Transaction as amended hereby.

1. *Amendments.* For each Unwind Date (as defined below), effective upon the closeout of GS&Co’s Hedge Positions on such Unwind Date, the Number of Warrants for each Component of the Transaction shall be reduced by 1/80<sup>th</sup> of the Daily Number of Warrants (as defined below) for such Unwind Date, with each such Number of Warrants rounded up to the nearest whole number, except that the Number of Warrants for the Component with the latest Expiration Date shall be reduced by the aggregate number resulting from such rounding.

2. *Amendment Payment.* In consideration of the amendments to the Transaction, Issuer agrees to pay to GS&Co. on each Payment Date (as defined below) an amount in USD (the “**Daily Amendment Payment**”) equal to the product of the Daily Number of Warrants for the related Unwind Date and the Amendment Payment Amount per Warrant (each as defined below); *provided* that the sum of the Daily Amendment Payments shall not exceed the Maximum Amendment Payment Amount (as defined below); *provided further*, that in lieu of payment in USD, Issuer may elect in its sole discretion to satisfy, with respect to any Unwind Date, the Daily Amendment Payment in Shares as provided in Annex B hereto.

Daily Number of Warrants: For any Unwind Date (as defined below), a number of Warrants as determined by GS&Co. with respect to which GS&Co. has closed out its Hedge Positions on such Unwind Date; *provided* that the sum of the Daily Number of Warrants shall not exceed the Maximum Number of Warrants (as defined below).

Maximum Number of Warrants:	76,749
Amendment Payment Amount per Warrant:	As set forth in Annex A, to be the amount specified for the relevant Unwind Period Price.
Maximum Amendment Payment Amount:	USD 23,985,597.48.
Payment Date:	For each Unwind Date, the third Currency Business Day following such Unwind Date.
Unwind Period:	A number of Scheduled Trading Days selected by GS&Co. in its sole discretion, beginning on the Scheduled Trading Day immediately following the date hereof, and ending no later than May 7, 2015.
Unwind Date:	Each Scheduled Trading Day during the Unwind Period on which GS&Co. has closed out its Hedge Positions in respect of Warrants.
Unwind Date Price:	For any Unwind Date, the volume-weighted average of the per Share prices at which GS&Co. purchases Shares in order to close out its Hedge Positions in respect of the Daily Number of Warrants on such Unwind Date; <i>provided</i> that GS&Co. shall not effect any such purchases at a price per Share in excess of the Limit Price.
Limit Price:	USD 408.00 per Share.

### 3. Representations and Warranties.

(a) Each party represents to the other party that:

(i) It is duly organized and validly existing under the laws of the jurisdiction of its organization or incorporation and, if relevant under such laws, in good standing.

(ii) It has the power to execute this Amendment and any other documentation relating to this Amendment to which it is a party, to deliver this Amendment and any other documentation relating to this Amendment that it is required by this Amendment to deliver and to perform its obligations under this Amendment and has taken all necessary action to authorize such execution, delivery and performance.

(iii) Such execution, delivery and performance do not violate or conflict with any law applicable to it, any provision of its constitutional documents, any order or judgment of any court or other agency of government applicable to it or any of its assets or any contractual restriction binding on or affecting it or any of its assets.

(iv) All governmental and other consents that are required to have been obtained by it with respect to this Amendment have been obtained and are in full force and effect and all conditions of any such consents have been complied with.

(v) Its obligations under this Amendment constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms (subject to applicable bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditors' rights generally and subject, as to enforceability,

to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law)).

(b) Issuer represents and warrants to and for the benefit of GS&Co. as follows:

(i) (A) On the date hereof, Issuer is not aware of any material non-public information regarding Issuer or the Shares and (B) its most recent Annual Report on Form 10-K, taken together with all reports and other documents subsequently filed by Issuer with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), when considered as a whole (with the more recent such reports and documents deemed to amend inconsistent statements contained in any earlier such reports and documents), does not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading.

(ii) On the date hereof and on the Payment Date, (A) the assets of Issuer at their fair valuation exceed the liabilities of Issuer, including contingent liabilities, (B) the capital of Issuer is adequate to conduct the business of Issuer and (C) Issuer has the ability to pay its debts and obligations as such debts mature and does not intend to, or does not believe that it will, incur debt beyond its ability to pay as such debts mature.

(iii) Issuer acknowledges its responsibilities under applicable federal securities laws, including, without limitation, Rule 10b-5 under the Exchange Act, in relation to the Transaction and its amendment.

(iv) Issuer is entering into this Amendment in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1 under the Exchange Act (“**Rule 10b5-1**”) or any other antifraud or anti-manipulation provisions of the federal or applicable state securities laws and that it has not entered into or altered and will not enter into or alter any corresponding or hedging transaction or position with respect to the Shares. Issuer acknowledges that it is the intent of the parties that this Amendment comply with the requirements of paragraphs (c)(1)(i)(A) and (B) of Rule 10b5-1 and this Amendment shall be interpreted to comply with the requirements of Rule 10b5-1(c).

(v) Issuer will not seek to control or influence GS&Co.’s decision to make any “purchases or sales” (within the meaning of Rule 10b5-1(c)(1)(i)(B)(3)) of Shares during the Unwind Period, including, without limitation, GS&Co.’s decision to enter into any hedging transactions. Issuer represents and warrants that it has consulted with its own advisors as to the legal aspects of its adoption and implementation of this Amendment under Rule 10b5-1.

(vi) Issuer acknowledges and agrees that any amendment, modification, waiver or termination of this Amendment must be effected in accordance with the requirements for the amendment or termination of a “plan” as defined in Rule 10b5-1(c). Without limiting the generality of the foregoing, any such amendment, modification, waiver or termination shall be made in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1, and no such amendment, modification or waiver shall be made at any time at which Issuer is aware of any material non-public information regarding Issuer or the Shares.

(vii) In the event Issuer elects to pay the Amendment Payment by delivering Shares in accordance with Annex B hereto, the representation and agreement set forth in Section 9.11 of the Equity Definitions shall be true and correct at the time of such delivery, excluding any representations therein relating to restrictions, obligations, limitations or requirements under applicable securities laws.

4. *Covenants of Issuer during Unwind Period.* Issuer agrees with GS&Co. that during the Unwind Period that:

(a) the Shares or securities that are convertible into, or exchangeable or exercisable for Shares, are not, and shall not be, subject to a “restricted period,” as such term is defined in Regulation M and (B) Issuer shall not engage in any “distribution,” as such term is defined in Regulation M until the second Exchange Business Day immediately following the Unwind Period;

(b) neither Issuer nor any “affiliated purchaser” (as defined in Rule 10b-18) shall directly or indirectly (including, without limitation, by means of any cash-settled or other derivative instrument) purchase, offer to purchase, place any bid or limit order that would effect a purchase of, or commence any tender offer relating to, any Shares (or an equivalent interest, including a unit of beneficial interest in a trust or limited partnership or a depository share) or any security convertible into or exchangeable or exercisable for Shares; *provided* that, for the avoidance of doubt, (i) for purposes of this Section 4(b) “affiliated purchaser” shall not include Sanofi or any of its directly or indirectly wholly owned subsidiaries; and (ii) this Section 4(b) shall not preclude Issuer from receiving (or retaining) any Shares in payment of the option exercise price or receiving (or retaining) any Shares in respect of tax withholding or other similar tax obligation in connection with the exercise, vesting or delivery of any awards granted under Issuer’s equity incentive award plans;

(c) it (A) will not make any public announcement (as defined in Rule 165(f) under the Securities Act) of any Merger Transaction or potential Merger Transaction unless such public announcement is made prior to the opening or after the close of the regular trading session on the Exchange for the Shares; and (B) shall promptly (but in any event prior to the next opening of the regular trading session on the Exchange) notify GS&Co. following any such announcement that such announcement has been made.

5. *GS&Co. Activities during Unwind Period.*

(a) GS&Co. agrees with Issuer that during the Unwind Period, GS&Co. shall use commercially reasonable efforts to make all purchases of Shares in a manner that would comply with the limitations set forth in clauses (b)(1), (b)(2), (b)(3), (b)(4) and (c) of Rule 10b-18, as if such rule were applicable to such purchases, taking into account any applicable Securities and Exchange Commission no-action letters as appropriate and subject to any delays between the execution and reporting of a trade of the Shares on the Exchange and other circumstances beyond GS&Co.’s control.

(b) GS&Co. and Issuer agree and acknowledge that any transactions with respect to the Shares (including, without limitation, any hedging transactions) entered into by GS&Co. during the Unwind Period are entered into for GS&Co.’s own account and on its own behalf and not for the account of, or on behalf of, Issuer.

6. *No Additional Amendments or Waivers.* Except as amended hereby, all the terms of the Transaction and provisions in the Confirmation shall remain and continue in full force and effect and are hereby confirmed in all respects.

7. *Counterparts.* This Amendment may be signed in any number of counterparts, each of which shall be an original, with the same effect as if all of the signatures thereto and hereto were upon the same instrument.

8. *Governing Law.* The provisions of this Amendment shall be governed by the New York law (without reference to choice of law doctrine).

Please confirm that the foregoing correctly sets forth the terms of our agreement by executing this Amendment and returning it in the manner indicated in the attached cover letter.

GOLDMAN, SACHS & CO.

By: /s/ Daniela A. Rouse

Name: Daniela A. Rouse

Title: Vice President

Agreed and Accepted By:

REGENERON PHARMACEUTICALS, INC.

By: /s/ Dominick Agron

Name: Dominick Agron

Title: Vice President & Treasurer

**Annex A**

<b><u>Unwind Date Price</u></b>	<b><u>Amendment Payment Amount Per Warrant</u></b>
\$370.00	\$274.55
\$375.00	\$279.54
\$380.00	\$284.53
\$385.00	\$289.52
\$390.00	\$294.55
\$395.00	\$299.54
\$400.00	\$304.53
\$405.00	\$309.52
\$408.00	\$312.52

For an Unwind Date Price falling between the amounts appearing in such column, the Amendment Payment Amount per Warrant will be calculated by GS&Co. using linear interpolation. If the Amendment Payment Amount per Warrant is otherwise not determinable pursuant to the foregoing because the Unwind Date Price is less than the lowest Unwind Date Price set forth above, the Amendment Payment Amount per Warrant will be determined by GS&Co. by linear extrapolation based on the two lowest Unwind Date Prices set forth above. If the Amendment Payment Amount per Warrant is otherwise not determinable pursuant to the foregoing because the Unwind Date Price is greater than the highest Unwind Date Price set forth above, the Amendment Payment Amount per Warrant will be determined by GS&Co. by linear extrapolation based on the two highest Unwind Date Prices set forth above.

## ANNEX B

### SHARE SETTLEMENT PROVISIONS

1. Payment of any Daily Amendment Payment in Shares by Issuer shall be made by delivery on the Payment Date of a number of Shares satisfying the conditions set forth in paragraph 2 below (the “**Registered Settlement Shares**”), or a number of Shares not satisfying such conditions (the “**Unregistered Settlement Shares**”), in either case with a value equal to such Daily Amendment Payment, with such Shares’ value determined by GS&Co. in good faith and in a commercially reasonable manner (which value shall, in the case of Unregistered Settlement Shares, take into account a commercially reasonable illiquidity discount).

2. Issuer may only deliver Registered Settlement Shares pursuant to paragraph 2 above if:

(a) a registration statement covering the public resale of the Registered Settlement Shares by GS&Co. (the “**Registration Statement**”) shall have been filed with the Securities and Exchange Commission under the Securities Act and been declared or otherwise become effective on or prior to the date of delivery, and no stop order shall be in effect with respect to the Registration Statement; a printed prospectus relating to the Registered Settlement Shares (including any prospectus supplement thereto, the “**Prospectus**”) shall have been delivered to GS&Co., in such quantities as GS&Co. shall reasonably have requested, on or prior to the date of delivery;

(b) the form and content of the Registration Statement and the Prospectus (including, without limitation, any sections describing the plan of distribution) shall be reasonably satisfactory to GS&Co.;

(c) as of or prior to the date of delivery, GS&Co. and its agents shall have been afforded a reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for underwritten offerings of equity securities and the results of such investigation are satisfactory to GS&Co., in its good faith discretion; and

(d) as of the date of delivery, an agreement (the “**Underwriting Agreement**”) shall have been entered into with GS&Co. in connection with the public resale of the Registered Settlement Shares by GS&Co. substantially similar to underwriting agreements customary for underwritten offerings of equity securities of a similar size by companies similar to Issuer, in form and substance reasonably satisfactory to GS&Co., which Underwriting Agreement shall include, without limitation, provisions substantially similar to those contained in such underwriting agreements for offerings of a similar size by companies similar to Issuer relating, without limitation, to the indemnification of, and contribution in connection with the liability of, GS&Co. and its affiliates and the provision of customary opinions, accountants’ comfort letters and lawyers’ negative assurance letters.

3. If Issuer delivers Unregistered Settlement Shares pursuant to paragraph 1 above:

(a) all Unregistered Settlement Shares shall be delivered to GS&Co. (or any affiliate of GS&Co. designated by GS&Co.) pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) thereof;

(b) as of or prior to the date of delivery, GS&Co. and any potential purchaser of any such Unregistered Settlement Shares from GS&Co. (or any affiliate of GS&Co. designated by GS&Co.) identified by GS&Co. shall be afforded a commercially reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for private placements of equity securities of a similar size by companies similar to Issuer (including, without limitation, the right to have made available to them for inspection all financial and other records, pertinent corporate documents and other information reasonably requested by them);

(c) as of the date of delivery, Issuer shall enter into an agreement (a “**Private Placement Agreement**”) with GS&Co. (or any affiliate of GS&Co. designated by GS&Co.) in connection with the private

placement of such Unregistered Settlement Shares by Issuer to GS&Co. (or any such affiliate) and the private resale of such Unregistered Settlement Shares by GS&Co. (or any such affiliate), substantially similar to private placement purchase agreements customary for private placements of equity securities of a similar size by companies similar to Issuer, in form and substance commercially reasonably satisfactory to GS&Co., which Private Placement Agreement shall include, without limitation, provisions substantially similar to those contained in such private placement purchase agreements for offerings of similar size by companies similar to Issuer relating, without limitation, to the indemnification of, and contribution in connection with the liability of, GS&Co. and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters, and shall provide for the payment by Issuer of all commercially reasonable fees and expenses in connection with such resale, including all commercially reasonable fees and expenses of counsel for GS&Co., and shall contain representations, warranties, covenants and agreements of Issuer reasonably necessary or advisable to establish and maintain the availability of an exemption from the registration requirements of the Securities Act for such resale; and

(d) in connection with the private placement of such shares by Issuer to GS&Co. (or any such affiliate) and the private resale of such shares by GS&Co. (or any such affiliate), Issuer shall, if so requested by GS&Co., prepare, in cooperation with GS&Co., a private placement memorandum in form and substance reasonably satisfactory to GS&Co. and customary for private placements of equity securities of similar size by companies similar to Issuer.

4. GS&Co., itself or through an affiliate (the "**Selling Agent**") or any underwriter(s), will sell, in a commercially reasonable manner and over a commercially reasonable period, all, or such lesser portion as may be required hereunder, of the Registered Settlement Shares or Unregistered Settlement Shares and any Makewhole Shares (as defined below) (together, the "**Settlement Shares**") delivered by Issuer to GS&Co. pursuant to paragraph 5 below in a commercially reasonable manner commencing on the date one Settlement Cycle following the Termination Date (such date, the "**Net Share Settlement Date**" for purposes of Net Share Settlement by Issuer) and continuing until the date on which the aggregate Net Proceeds (as such term is defined below) of such sales, as determined by GS&Co. in a commercially reasonable manner, is equal to the Amendment Payment (such date, the "**Final Resale Date**"). If the proceeds of any sale(s) made by GS&Co., the Selling Agent or any underwriter(s), net of any commercially reasonable fees and commissions (including, without limitation, commercially reasonable underwriting or placement fees) customary for similar transactions of a similar size under the circumstances at the time of the offering, together with commercially reasonable carrying charges and expenses incurred in connection with the offer and sale of the Shares (including, but without limitation to, the covering of any over-allotment or short position (syndicate or otherwise)) (the "**Net Proceeds**") exceed the Amendment Payment, GS&Co. will refund, in USD, such excess to Issuer on the date that is three (3) Currency Business Days following the Final Resale Date, and, if any portion of the Settlement Shares remains unsold, GS&Co. shall return to Issuer on that date such unsold Shares.

5. If the Calculation Agent determines that the Net Proceeds received from the sale of the Registered Settlement Shares or Unregistered Settlement Shares or any Makewhole Shares, if any, pursuant to this paragraph 5 are less than the Amendment Payment (the amount in USD by which the Net Proceeds are less than the Amendment Payment being the "**Shortfall**" and the date on which such determination is made, the "**Deficiency Determination Date**"), Issuer shall on the Exchange Business Day next succeeding the Deficiency Determination Date (the "**Makewhole Notice Date**") deliver to GS&Co., through the Selling Agent, a notice of Issuer's election that Issuer shall either (i) pay an amount in cash equal to the Shortfall on the day that is one (1) Currency Business Day after the Makewhole Notice Date, or (ii) deliver additional Shares. If Issuer elects to deliver to GS&Co. additional Shares, then Issuer shall deliver additional Shares in compliance with the terms and conditions of paragraph 2 or paragraph 3 above, as the case may be (the "**Makewhole Shares**"), on the first Clearance System Business Day which is also an Exchange Business Day following the Makewhole Notice Date in such number as the Calculation Agent commercially reasonably believes would have a market value on that Exchange Business Day equal to the Shortfall. Such Makewhole Shares shall be sold by GS&Co. in accordance with the provisions above; *provided* that if the sum of the Net Proceeds from the sale of the originally delivered Shares and the Net Proceeds from the sale of any Makewhole Shares is less than the Amendment Payment then Issuer shall, at its election, either make such cash payment or deliver to GS&Co. further Makewhole Shares until such Shortfall has been reduced to zero.

6. Notwithstanding the foregoing, and without limiting the Issuer's ability to elect to settle any Daily Amendment Payment in Shares, as provided in this Annex B, in no event shall the aggregate number of Settlement

Shares and Makewhole Shares required to be delivered by the Issuer upon settlement of all Daily Amendment Payments so settled in Shares, in the aggregate, be greater than 250,000 Shares (the “**Maximum Number of Shares**”). For the avoidance of doubt, in no event will the Company be required to deliver cash in the event the aggregate number of Settlement Shares and Makewhole Shares required to be delivered by the Issuer upon settlement of all Daily Amendment Payments so settled in Shares, in the aggregate, would, but for the foregoing sentence, exceed the Maximum Number of Shares.

**Certification of Principal Executive Officer Pursuant to  
Rule 13a-14(a) under the Securities Exchange Act  
of 1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2015

/s/ Leonard S. Schleifer  
Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

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**Certification of Principal Financial Officer Pursuant to  
Rule 13a-14(a) under the Securities Exchange Act  
of 1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Robert E. Landry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2015

/s/ Robert E. Landry

Robert E. Landry

Senior Vice President, Finance and Chief

Financial Officer

(Principal Financial Officer)

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**Certification of Principal Executive Officer and Principal Financial Officer Pursuant to  
18 U.S.C. Section 1350,  
As Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (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.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)  
May 7, 2015

/s/ Robert E. Landry

Robert E. Landry  
Senior Vice President, Finance and Chief  
Financial Officer  
(Principal Financial Officer)  
May 7, 2015