# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	FORM 10-Q		
Mark One)			
<b>☑</b> QUARTERLY REPORT 934	PURSUANT TO SECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE	E ACT OF
	For the quarterly period ended June 30, 2016  OR		
☐ TRANSITION REPORT	PURSUANT TO SECTION 13 OR 15 (d) OF THE	E SECURITIES EXCHANG	E ACT OF
(2 <b>54</b>	For the transition period from to  Commission File Number: 001-36065		
	ACCELERON PHARMA INC (Exact name of registrant as specified in its charter)	•	
<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	2836 (Primary Standard Industrial Classification Code Number)	<b>27-0072226</b> (I.R.S. Employer Identification Number	r)
	128 Sidney Street Cambridge, MA 02139 (617) 649-9200  (Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)	ng	
Indicate by check mark whether the regularing the preceding 12 months (or for such so the past 90 days. Yes ⊠ No □	gistrant: (1) has filed all reports required to be filed by Section 13 of shorter period that the registrant was required to file such reports),	or 15(d) of the Securities Exchange A and (2) has been subject to such filing	ct of 1934 g requirements
o be submitted and posted pursuant to Rule 4	gistrant has submitted electronically and posted on its corporate We 105 of Regulation S-T during the preceding 12 months (or for such No $\Box$		
	gistrant is a large accelerated filer, an accelerated filer, a non-accelerated filer" and "smaller reporting company" in Rule 12b-2 of the		npany. See the
Large accelerated filer		Accelerated filer	
Non-accelerated filer	ot check if a smaller reporting company)	Smaller reporting company	
Indicate by check mark whether the reg	gistrant is a shell company (as defined in Rule 12b-2 of the Exchan	ge Act). Yes □ No ⊠	
As of July 31, 2016, there were 37,596	5,691 shares of the registrant's Common Stock, par value \$0.001 pe	er share, outstanding.	

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# Acceleron Pharma Inc.

# **Condensed Consolidated Balance Sheets**

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

(unaudited)

		June 30, 2016	Г	December 31, 2015
Assets				
Current assets:				
Cash and cash equivalents	\$	36,995	\$	27,783
Collaboration receivables (all amounts are with related party)		3,239		3,628
Prepaid expenses and other current assets		3,081		2,458
Short-term investments		83,724		77,064
Total current assets		127,039		110,933
Property and equipment, net		4,190		3,106
Restricted cash		996		796
Other assets		8		368
Long-term investments		141,997		31,134
Total assets	\$	274,230	\$	146,337
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	566	\$	875
Accrued expenses		11,824		12,400
Deferred revenue		541		555
Deferred rent		762		661
Total current liabilities		13,693		14,491
Deferred revenue, net of current portion		3,973		4,239
Deferred rent, net of current portion		1,340		1,157
Warrants to purchase common stock		11,368		17,187
Total liabilities		30,374		37,074
Commitments and contingencies (Note 14)				
Stockholders' equity:				
Undesignated preferred stock, \$0.001 par value: 25,000,000 shares authorized and no shares issued or outstanding		_		_
Common stock, \$0.001 par value: 175,000,000 shares authorized; 37,328,903 and 33,313,355 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively		38		34
Additional paid-in capital		567,999		416,926
Accumulated deficit		(324,433)		(307,477)
Accumulated other comprehensive income (loss)		252		(220)
Total stockholders' equity		243,856		109,263
Total liabilities and stockholders' equity	\$	274,230	\$	146,337
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See accompanying notes to these condensed consolidated financial statements.

#### **Acceleron Pharma Inc.**

# **Condensed Consolidated Statements of Operations and Comprehensive Loss**

# (amounts in thousands except per share data)

# (unaudited)

		Three Months	Ended	l June 30,		Six Months Ended June 30,			
		2016		2015		2016		2015	
Revenue:									
Collaboration revenue:									
License and milestone	\$	135	\$	431	\$	15,279	\$	803	
Cost-sharing, net		3,060		5,286		6,117		9,336	
Total revenue (all amounts are with related party)		3,195		5,717		21,396		10,139	
Costs and expenses:	,					_		_	
Research and development		16,138		14,150		32,390		28,930	
General and administrative		6,712		4,661		12,618		9,360	
Total costs and expenses		22,850		18,811		45,008		38,290	
Loss from operations		(19,655)		(13,094)		(23,612)		(28,151)	
Other (expense) income, net:									
Other (expense) income, net		(2,864)		2,557		5,819		2,979	
Interest income		503		154		837		217	
Total other (expense) income, net	,	(2,361)		2,711		6,656		3,196	
Net loss applicable to common stockholders	\$	(22,016)	\$	(10,383)	\$	(16,956)	\$	(24,955)	
Net loss per share applicable to common stockholders-basic and diluted									
(Note 9)	\$	(0.59)	\$	(0.32)	\$	(0.46)	\$	(0.76)	
Weighted-average number of common shares used in computing net loss per									
share applicable to common stockholders-basic and diluted		37,272		32,870		37,092		32,754	
Other comprehensive loss:									
Net loss	\$	(22,016)	\$	(10,383)	\$	(16,956)	\$	(24,955)	
Net unrealized holding gains (losses) on short-term and long-term	Ψ	(22,010)	Ψ	(10,303)	Ψ	(10,730)	Ψ	(24,755)	
investments during the period		227		(19)		472		(62)	
Comprehensive loss	\$	(21,789)	\$	(10,402)	\$	(16,484)	\$	(25,017)	
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See accompanying notes to these condensed consolidated financial statements.

#### Acceleron Pharma Inc.

#### **Condensed Consolidated Statements of Cash Flows**

#### (amounts in thousands)

#### (unaudited)

Six Months Ended June 30, 2016 2015 **Operating Activities** \$ Net loss (16,956)(24,955)Adjustments to reconcile net loss to net cash used in operating activities: 715 574 Depreciation and amortization 19 12 Loss on disposition of fixed assets Stock-based compensation 8,800 5,231 Change in fair value of warrants (5.819)(2,979)Net amortization of premium on investments (432)(777)Changes in assets and liabilities: (619)648 Prepaid expenses and other assets 389 Collaboration receivables (1,919)Accounts payable (309)1,066 Accrued expenses (525)1,373 Restricted cash (200)Deferred revenue (280)(803)Deferred rent 284 (244)Net cash used in operating activities (14,933)(22,773)**Investing Activities** Purchase of investments (160,798)(132,709)Proceeds from maturities of investments 14,985 44,178 Purchases of property and equipment (244)(1,560)Net cash used in investing activities (118,180)(117,968)**Financing Activities** Proceeds from issuance of common stock from public offering, net issuance costs 140,391 Proceeds from exercise of stock options and warrants to purchase common stock 1,550 2,130 Proceeds from issuances of common stock related to employee stock purchase plan 384 307 Net cash provided by financing activities 142,325 2,437 Net increase (decrease) in cash and cash equivalents 9,212 (138,304)Cash and cash equivalents at beginning of period 27,783 176,460 Cash and cash equivalents at end of period \$ 36,995 \$ 38,156 Supplemental Disclosure of Non-Cash Investing and Financing Activities: Reclassification of warrant liability to additional paid-in capital \$ 465 Purchase of property and equipment included in accounts payable and accrued expenses \$ \$ 258 157

See accompanying notes to these condensed consolidated financial statements.

#### Acceleron Pharma Inc.

# Notes to Condensed Consolidated Financial Statements (unaudited)

#### 1. Nature of Business

Acceleron Pharma Inc. (Acceleron or the Company) is a Cambridge, Massachusetts-based clinical stage biopharmaceutical company focused on the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. The Company's research focuses on key natural regulators of cellular growth and repair, particularly the Transforming Growth Factor-Beta (TGF-beta) protein superfamily. By combining its discovery and development expertise, including its proprietary knowledge of the TGF-beta superfamily, and its internal protein engineering and manufacturing capabilities, the Company has built a highly productive discovery and development platform that has generated innovative therapeutic candidates with novel mechanisms of action. The Company has four internally discovered therapeutic candidates that are currently in clinical trials.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risk that the Company never achieves profitability, the need for substantial additional financing, risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology and compliance with government regulations.

#### 2. Basis of Presentation

The accompanying interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

The accompanying interim condensed consolidated financial statements are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2015, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2016, and the results of its operations and its cash flows for the three and six months ended June 30, 2016 and 2015.

The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, together with Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

On January 11, 2016, the Company completed its underwritten public offering of 3,750,000 shares of common stock at a public offering price of \$40.00 per share. The aggregate net proceeds received by the Company, after underwriting discounts and commissions and other offering expenses, were \$140.3 million.

The accompanying interim condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the financial statements. As of June 30, 2016, the Company's significant accounting policies and estimates, which are detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, have not changed.

### 3. Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts expensed during the reporting period.

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of

reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the consolidated financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: revenue recognition, stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of liability-classified warrants, accrued expenses, and the recoverability of the Company's net deferred tax assets and related valuation allowance.

#### 4. Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment, which is the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. The Company does use contract research organizations and research institutions located outside the United States. Some of these expenses are subject to collaboration reimbursement which is presented as a component of cost sharing, net in the consolidated statements of operations and comprehensive loss.

#### 5. Cash Equivalents and Short-term and Long-term Investments

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held primarily in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified all of its marketable securities at June 30, 2016 as "available-for-sale" pursuant to ASC 320, *Investments – Debt and Equity Securities*. The Company records available-for-sale securities at fair value, with the unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders' equity. There were no realized gains or losses on marketable securities for the three and six months ended June 30, 2016 and 2015.

Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities.

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion in interest income. The cost of securities sold is based on the specific identification method. The Company includes in interest income interest and dividends on securities classified as available-for-sale.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

The following is a summary of cash, cash equivalents and investments as of June 30, 2016 and December 31, 2015 (in thousands):

	June 30, 2016							
	Amortized Cost			Gross Unrealized Gains		Gross Unrealized Losses		imated Fair Value
Cash and cash equivalents due in 90 days or less	\$	36,995	\$	_	\$	_	\$	36,995
Available-for-sale securities:								
Corporate obligations due in one year or less		45,836		10		(10)		45,836
Corporate obligations due in more than one year		53,187		155		(9)		53,333
U.S. Treasury securities due in one year or less		7,497		7		_		7,504
U.S. Treasury securities due in more than one year		26,535		86		_		26,621
Certificates of deposit due in one year or less		19,116		_		_		19,116
Certificates of deposit due in more than one year		11,746		_		_		11,746
Mortgage and other asset backed securities due in one year or less		11,267		3		(2)		11,268
Mortgage and other asset backed securities due in more than one year		50,285		18		(6)		50,297
Total available-for-sale securities		225,469		279		(27)		225,721
Total cash, cash equivalents and available-for-sale securities	\$	262,464	\$	279	\$	(27)	\$	262,716

	December 31, 2015								
		ortized Cost	Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value		
Cash and cash equivalents due in 90 days or less	\$	27,783	\$	_	\$		\$	27,783	
Available-for-sale securities:									
Corporate obligations due in one year or less		53,243		_	(	(81)	\$	53,162	
Corporate obligations due in more than one year		14,112		_	(	(72)		14,040	
U.S. Treasury securities due in one year or less		6,016		_		(4)		6,012	
U.S. Treasury securities due in more than one year		4,995		_	(	(15)		4,980	
Certificates of deposit due in one year or less		11,890		_		_		11,890	
Certificates of deposit due in more than one year		4,886		_		_		4,886	
Mortgage and other asset backed securities due in one year or less		6,010		_	(	(10)		6,000	
Mortgage and other asset backed securities due in more than one year		7,266		_	(	(38)		7,228	
Total available-for-sale securities	\$	108,418	\$		\$ (2	220)	\$	108,198	
Total cash, cash equivalents and available-for-sale securities	\$	136,201	\$	_	\$ (2	220)	\$	135,981	

# 6. Restricted Cash

As of June 30, 2016 the Company maintained letters of credit totaling \$1.0 million held in the form of certificates of deposit and money market funds as collateral for the Company's facility lease obligations and its credit cards. As of December 31, 2015, the Company maintained letters of credit totaling \$0.8 million held in the form of certificates of deposit.

#### 7. Concentrations of Credit Risk and Off-Balance Sheet Risk

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, restricted cash, short-term and long-term investments and collaboration receivables. The Company maintains its cash and cash equivalent balances and short-term and long-term investments with financial institutions that management believes are creditworthy. Short-term and long-term investments consist of investment grade corporate obligations, treasury notes, asset backed securities, and certificates of deposit. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentrations of credit risk.

The Company routinely assesses the creditworthiness of its customers and collaboration partners. The Company has not experienced any material losses related to receivables from individual customers and collaboration partners, or groups of customers. The Company does not require collateral. Due to these factors, no additional credit risk beyond amounts provided for collection losses is believed by management to be probable in the Company's collaboration receivables.

#### 8. Fair Value Measurements

The following tables set forth the Company's financial instruments carried at fair value using the lowest level of input applicable to each financial instrument as of June 30, 2016 and December 31, 2015 (in thousands):

	June 30, 2016										
	Quoted Prices in Active Markets for Identical Items (Level 1)		Observable Uno Inputs I		Significant Unobservable Inputs (Level 3)		Total				
Assets:											
Money market funds	\$	35,292	\$	_	\$	_	\$	35,292			
Corporate obligations		_		101,172		_		101,172			
U.S. Treasury securities		_		34,125		_		34,125			
Certificates of deposit		_		30,862		_		30,862			
Mortgage and other asset backed securities		_		61,565				61,565			
Restricted cash		996		_		_		996			
Total assets	\$	36,288	\$	227,724	\$		\$	264,012			
Liabilities:											
Warrants to purchase common stock	\$	_	\$	_	\$	11,368	\$	11,368			
Total liabilities	\$	_	\$	_	\$	11,368		11,368			

				December 3	1, 201	15	
	Quoted Prices in Active Marke for Identical Iten (Level 1)			Significant other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)	Total
Assets:							
Money market funds	\$	24,811	\$		\$	_	\$ 24,811
Corporate obligations		_		67,706		_	67,706
U.S. Treasury securities				10,991			10,991
Certificates of deposit		_		16,776		_	16,776
Mortgage and other asset backed securities		_		13,228		_	13,228
Restricted cash		796		_		_	796
Total assets	\$	25,607	\$	108,701	\$	_	\$ 134,308
Liabilities:	====						
Warrants to purchase common stock	\$	_	\$		\$	17,187	\$ 17,187
Total liabilities	\$		\$		\$	17,187	\$ 17,187

The money market funds noted above are included in cash and cash equivalents in the accompanying balance sheets. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the six months ended June 30, 2016 or the year ended December 31, 2015.

Items measured at fair value on a recurring basis include warrants to purchase common stock (Note 13). During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs.

The following table sets forth a summary of changes in the fair value of the Company's common stock warrant liability, which has been classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

	 Six Months Ended June 30,					
	2016		2015			
Beginning balance	\$ 17,187	\$	14,124			
Change in fair value	(5,819)		(2,979)			
Exercises	_		(465)			
Repurchases	_		_			
Conversions	_		_			
Ending balance	\$ 11,368	\$	10,680			

The fair value of the warrants to purchase common stock on the date of issuance and on each re-measurement date for those warrants classified as liabilities was estimated using either the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock, or for certain re-measurement dates, when the warrants are deeply in the money, the Black-Scholes option pricing model. At each reporting period the Company evaluates the best valuation methodology, and at June 30, 2016, the Monte Carlo simulation framework was used. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The Company measures eligible assets and liabilities at fair value, with changes in value recognized in earnings. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to re-measure any of its existing financial assets or liabilities, and did not elect the fair value option for any financial assets and liabilities transacted in the six months ended June 30, 2016 or the year ended December 31, 2015.

#### 9. Net Loss Per Share

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because their inclusion would have had an anti-dilutive effect (in thousands):

	Three Months June 30		Six Months Ended June 30,			
	2016	2015	2016	2015		
Outstanding stock options	3,503	3,477	3,503	3,477		
Common stock warrants	397	400	397	400		
Shares issuable under employee stock purchase plan	13	11	13	11		
Restricted stock units	608	28	608	28		
	4,521	3,916	4,521	3,916		

#### 10. Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, other events, and circumstances from non-owner sources. Accumulated other comprehensive income (loss) is presented separately on the consolidated balance sheets and consists entirely of cumulative unrealized gains and losses from short-term and long-term investments as of June 30, 2016.

### 11. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company has evaluated all subsequent events and determined that there are no material recognized or unrecognized subsequent events requiring disclosure.

#### 12. Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the

company expects to receive for those goods or services. The new standard will be effective for the Company on January 1, 2018. The Company is currently evaluating the method of adoption and the potential impact that Topic 606 may have on its financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40)*. The ASU requires all entities to evaluate for the existence of conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of the financial statements. The accounting standard is effective for interim and annual periods ending after December 15, 2016, and will not have a material impact on the consolidated financial statements, but may impact the Company's footnote disclosures.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810), Amendments to the Consolidation Analysis, which updated accounting guidance on consolidation requirements. This update changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. This guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015, with early adoption permitted. The Company adopted this standard on January 1, 2016 and the adoption did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740)*, *Balance Sheet Classification of Deferred Taxes*. The new standard requires that deferred tax assets and liabilities be classified as non-current in a classified statement of financial position. The new standard will be effective for the Company on January 1, 2017. The Company is currently evaluating the method of adoption and the potential impact that Topic 740 may have on its financial position and results of operations.

In February 2016 the FASB issued ASU 2016-02, *Leases (Topic 842), Amendments to the FASB Accounting Standards Codification,* which replaces the existing guidance for leases. ASU 2016-02 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a twelve month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. In addition, ASU 2016-02 requires the use of the modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. This guidance is effective for annual and interim periods beginning after December 15, 2018 and requires retrospective application. The Company is currently assessing the impact that adopting ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In March 2016 the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share based payments, including income tax consequences, classification of awards as either equity, or liabilities, an option to make a policy election to recognize gross share based compensation expense with actual forfeitures recognized as they occur as well as certain classification changes on the statement of cash flows. This guidance is effective for annual and interim reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is currently assessing the impact that adopting ASU 2016-09 will have on its consolidated financial statements and related disclosures.

#### 13. Warrants

Below is a summary of the number of shares issuable upon exercise of outstanding warrants and the terms and accounting treatment for the outstanding warrants (in thousands, except per share data):

		Warrants as of				
			Weighted- Average Exercise			ce Sheet ification
	June 30, 2016	December 31, 2015	Price Per Share	Expiration	June 30, 2016	December 31, 2015
Warrants to purchase common stock	393	393	\$ 5.88	June 10, 2020 - July 9, 2020	Liability	Liability
Warrants to purchase common stock	4	5	4.00 - 7.40	March 28, 2017 - December 31, 2017	Equity(1)(2)	Equity(2)
All warrants	397	398	\$ 5.88			

- (1) In March 2016, the warrant holders exercised warrants to purchase 1,317 shares of Common Stock on a net basis, resulting in the issuance of 1,109 shares of Common Stock.
- (2) Warrants to purchase common stock were issued in connection with various debt financing transactions that were consummated in periods prior to December 31, 2012. See discussion below for further details.

In connection with the Series E redeemable convertible preferred stock (Series E Preferred Stock) financing transactions that took place in June 2010 and July 2010, the Company issued warrants to purchase up to 871,580 shares of common stock. Each warrant was immediately exercisable and expires ten years from the original date of issuance. The warrants to purchase shares of the Company's common stock have an exercise price equal to the estimated fair value of the underlying instrument as of the initial date such warrants were issued. Each warrant is exercisable on either a physical settlement or net share settlement basis from the date of issuance. The warrant agreement contains a provision requiring an adjustment to the number of shares in the event the Company issues common stock. or securities convertible into or exercisable for common stock, at a price per share lower than the warrant exercise price. The Company concluded the anti-dilution feature required the warrants to be classified as liabilities under ASC Topic 815, Derivatives and Hedging—Contracts in Entity's Own Equity (ASC 815). The warrants are measured at fair value, with changes in fair value recognized as a gain or loss to other income (expense) in the statements of operations and comprehensive income (loss) for each reporting period thereafter. The fair value of the common stock warrants were recorded as a discount to the preferred stock issued of \$3.0 million, and the preferred stock was being accreted to the redemption value. At the end of each reporting period or through the life of the instrument, the Company re-measured the fair value of the outstanding warrants, using current assumptions, resulting in an increase in fair value of \$2.9 million and a decrease of \$2.6 million for the three months ended June 30, 2016 and 2015, respectively, and a decrease in fair value of \$5.8 million and \$3.0 million for the six months ended June 30, 2016 and 2015, respectively, which was recorded in other (expense) income in the accompanying consolidated statements of operations and comprehensive loss. The Company will continue to re-measure the fair value of the liability associated with the warrants to purchase common stock at the end of each reporting period until the earlier of the exercise or the expiration of the applicable warrants. All remaining outstanding warrants were fully vested and exercisable as of June 30, 2016 and December 31, 2015.

#### 14. Commitments and Contingencies

#### Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the three months ended June 30, 2016, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

#### Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met at June 30, 2016 and December 31, 2015, or royalties on future sales of specified products. No royalty payments under these agreements are expected to be payable in the immediate future. See Note 15 for discussion of these arrangements.

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

#### 15. Significant Agreements

# Celgene

#### Overview

On February 20, 2008 the Company entered into a collaboration, license, and option agreement with Celgene Corporation (Celgene) relating to sotatercept (the Sotatercept Agreement). On August 2, 2011, the Company entered into a second collaboration, license and option agreement with Celgene for luspatercept (the Luspatercept Agreement), and also amended certain terms of the Sotatercept Agreement. These agreements provide Celgene exclusive licenses for sotatercept and luspatercept in all indications, as well as exclusive rights to obtain a license to certain future compounds. Celgene is an

integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

There have been no material changes to the key terms of the Sotatercept and Luspatercept Agreements since December 31, 2015. For further information on the terms of the agreements as well as the historical accounting analysis, please see the notes to the consolidated financial statements included in the Company's Form 10-K for the year ended December 31, 2015.

#### Sotatercept Agreement

Under the terms of the Sotatercept Agreement, the Company and Celgene collaborate worldwide for the joint development and commercialization of sotatercept. The Company also granted Celgene an option to license three discovery stage compounds. Under the terms of the agreement, the Company and Celgene will jointly develop, manufacture and commercialize sotatercept.

The Company retained responsibility for research and development through the end of Phase 2a clinical trials, as well as manufacturing the clinical supplies for these trials. These activities were substantially completed in 2011. Celgene is conducting the ongoing Phase 2 trials and will be responsible for any Phase 3 clinical trials, as well as additional Phase 2 clinical trials, and will be responsible for overseeing the manufacture of Phase 3 and commercial supplies by third party contract manufacturing organizations.

Through June 30, 2016, the Company has received \$43.3 million in research and development funding and milestone payments for sotatercept under the original and modified agreements. The next likely clinical milestone payment would be \$10.0 million and result from Celgene's start of a Phase 3 study in chronic kidney disease.

#### Luspatercept Agreement

Under the terms of the Luspatercept Agreement, the Company and Celgene collaborate worldwide for the joint development and commercialization of luspatercept. The Company also granted Celgene an option for future products for which Acceleron files an Investigational New Drug application for the treatment of anemia.

The Company retains responsibility for research and development through the end of Phase 1 and initial Phase 2 clinical trials, as well as manufacturing the clinical supplies for these studies. Celgene will conduct subsequent Phase 2 and Phase 3 clinical studies. Acceleron will manufacture luspatercept for the Phase 1 and Phase 2 clinical trials and Celgene will be responsible for overseeing the manufacture of Phase 3 and commercial supplies by third party contract manufacturing organizations.

Through June 30, 2016, the Company has received \$81.6 million in research and development funding and milestone payments for luspatercept. The next likely clinical milestone payment would be \$25.0 million and result from U.S. Food and Drug Administration or European Medical Association acceptance of a Biologics Licensing Application or equivalent for luspatercept in either myelodysplastic syndromes or beta-thalassemia. The Company has not yet identified additional compounds for the treatment of anemia. Accordingly, there is no assurance that the Company will generate future value from additional programs.

### **Both Agreements**

The Company and Celgene shared development costs under the Sotatercept and Luspatercept Agreements through December 31, 2012. As of January 1, 2013, Celgene has been responsible for paying 100% of worldwide development costs under both agreements. Celgene will be responsible for all commercialization costs worldwide. The Company has the right to co-promote sotatercept, luspatercept and future products under both agreements in North America. Celgene's option to buy down royalty rates for sotatercept and luspatercept expired unexercised and, therefore, the Company will receive tiered royalties in the low-to-mid twenty percent range on net sales of sotatercept and luspatercept. The royalty schedules for sotatercept and luspatercept are the same.

### Accounting Analysis

During the three months ended June 30, 2016 and 2015, the Company recognized \$0.1 million and \$0.4 million, respectively, and during the six months ended June 30, 2016 and 2015, \$0.3 million and \$0.8 million, respectively, of the total deferred revenue as license and milestone revenue in the accompanying consolidated statements of operations and comprehensive loss.

As noted above, under the terms of the Luspatercept Agreement the Company retained responsibility for certain research and development activities through the completion of Phase 1 and initial Phase 2 clinical trials, as well as manufacturing the clinical supplies for these studies. Celgene is responsible for the conduct of subsequent Phase 2 and Phase 3 clinical studies. In November 2013, the Company agreed to conduct additional activities for the benefit of the luspatercept program including certain clinical and non-clinical services such as multiple toxicology studies and associated assay development and sample testing, clinical extension studies, and market development work. These activities are reimbursed under the same terms and rates of the existing Agreements. The Company evaluated the additional services to be provided and determined that as the Company is under no obligation to conduct these additional activities, these services do not represent a deliverable under or modification to the Luspatercept Agreement, but rather, represent a separate services arrangement which should be accounted for as the services are delivered.

Pursuant to the terms of the agreement, Celgene and the Company shared development costs, with Celgene responsible for substantially more than half of the costs for sotatercept and luspatercept until December 31, 2012 and 100% of the costs from January 1, 2013 and thereafter. Payments from Celgene with respect to research and development costs incurred by the Company are recorded as cost-sharing revenue. Payments by the Company to Celgene for research and development costs incurred by Celgene are recorded as a reduction to cost-sharing revenue. The Company recorded net cost-sharing revenue of \$3.1 million and \$5.3 million during the three months ended June 30, 2016 and 2015, respectively, and \$6.1 million and \$9.3 million during the six months ended June 30, 2016 and 2015, respectively.

#### Other Agreements

#### Other

In 2004, the Company entered into a license agreement with a non-profit institution for an exclusive, sublicensable, worldwide, royalty-bearing license to certain patents developed by the institution (Primary Licensed Products). In addition, the Company was granted a non-exclusive, non-sub-licensable license for Secondary Licensed Products. As compensation for the licenses, the Company issued 62,500 shares of its common stock to the institution, the fair value of which was \$25,000, and was expensed during 2004 to research and development expense. The Company also agreed to pay specified development milestone payments totaling up to \$2.0 million for sotatercept and \$0.7 million for luspatercept. In addition, the Company is obligated to pay milestone fees based on the Company's research and development progress, and U.S. sublicensing revenue ranging from 10% - 25%, as well as a royalty ranging from 1.0% - 3.5% of net sales on any products under the licenses. During the three months ended June 30, 2016 and 2015, the Company expensed \$0.1 million and \$0.1 million, respectively, and during the six months ended June 30, 2016 and 2015, respectively, the Company expensed \$1.0 million and \$0.1 million of milestones and fees defined under the agreement.

In 2004, the Company entered into another license agreement with certain individuals for an exclusive, sublicensable, worldwide, royalty-bearing license to certain patents developed by the individuals. The Company agreed to pay specified development and sales milestone payments aggregating up to \$1.0 million relating to the development and commercialization of dalantercept. In addition, the Company is required to pay royalties in the low single-digits on worldwide net product sales of dalantercept, with royalty obligations continuing at a 50% reduced rate for a period of time after patent expiration. If the Company sublicenses its patent rights, it will owe a percentage of sublicensing revenue, excluding payments based on the level of sales, profits or other levels of commercialization. During the three and six months ended June 30, 2016 and 2015, the Company did not reach any milestones defined under the agreement and, therefore, no amounts have been paid or expensed.

During 2012, the Company executed a license agreement with a research institution for an exclusive, sublicensable, worldwide, royalty-bearing license. The Company is obligated to pay development milestones and commercial milestone fees relating to dalantercept totaling up to \$1.0 million. The Company will also pay \$25,000 annually upon first commercial sale as well as royalties of 1.5% of net sales on any products developed under the patents. During the three and six months ended June 30, 2016 and 2015, the Company did not reach any milestones defined under the agreement and, therefore, no amounts have been paid or expensed.

In May 2014, the Company executed a collaboration agreement with a research technology company. The Company paid an upfront research fee of \$0.3 million upon execution of the agreement. The Company also received an option to obtain a commercial license to the molecules developed during the collaboration. During the three months ended June 30, 2016 and 2015, the Company expensed \$0.2 million and \$0.4 million, respectively, and during the six months ended June 30, 2016 and 2015, the Company expensed \$0.5 million and \$0.8 million, respectively, of milestones and fees, which is recorded as research and development expense.

#### 16. Stock-Based Compensation

The Company recognized stock-based compensation expense related to stock options, restricted stock units and the 2013 Employee Stock Purchase Plan (2013 ESPP) totaling \$4.6 million , \$2.7 million , \$8.8 million and \$5.2 million during the three months ended June 30, 2016 and 2015 and the six months ended June 30, 2016 and 2015, respectively.

Total compensation cost recognized for all stock-based compensation awards in the consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Three Months Ended June 30,					Six Months Ended June 30,				
		2016		2015		2016		2015		
Research and development	\$	1,850	\$	1,019	\$	3,676	\$	2,101		
General and administrative		2,701		1,641		5,124		3,130		
	\$	4,551	\$	2,660	\$	8,800	\$	5,231		

#### **Stock Options**

The fair value of each stock option issued to employees was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

		Three Months Ended June 30,		nded
	2016	2015	2016	2015
Expected volatility	64.5%	66.8%	64.4%	67.1%
Expected term (in years)	6.0	6.0	5.9	6.0
Risk-free interest rate	1.5%	1.6%	1.4%	1.7%
Expected dividend yield	<del></del> %	%	%	%

The following table summarizes the stock option activity under the Company's 2003 Stock Option and Restricted Stock Plan and 2013 Equity Incentive Plan during the six months ended June 30, 2016 (in thousands):

	Number of Grants	Weighted- Average Exercise Price Per Share	Weighted- Average Contractual Life (in years)	l	ggregate ntrinsic Value(1)
Outstanding at December 31, 2015	3,191	\$ 18.85	6.31		
Granted	582	\$ 28.23			
Exercised	(247)	\$ 6.28			
Canceled or forfeited	(23)	\$ 35.09			
Outstanding at June 30, 2016	3,503	\$ 21.18	6.62	\$	51,317
Exercisable at June 30, 2016	2,093	\$ 14.21	5.19	\$	43,957
Vested and expected to vest at June 30, 2016 (2)	3,449	\$ 21.01	6.58	\$	51,101

- (1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money at June 30, 2016.
- (2) This represents the number of vested options at June 30, 2016, plus the number of unvested options expected to vest at June 30, 2016, based on the unvested options outstanding at June 30, 2016, adjusted for the estimated forfeiture rate.

During the six months ended June 30, 2016, the Company granted stock options to purchase an aggregate of 582,240 shares of its common stock, with a weighted-average grant date fair value of options granted of \$28.23.

During the six months ended June 30, 2016, current and former employees of the Company exercised a total of 246,727 options, resulting in total proceeds of \$1.6 million.

The aggregate intrinsic value of options exercised during the six months ended June 30, 2016 was \$6.4 million.

As of June 30, 2016, there was \$23.5 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over

#### **Restricted Stock Units**

The following table summarizes the restricted stock unit (RSU) activity under the 2013 Equity Incentive Plan during the six months ended June 30, 2016 (in thousands):

	Number of Grants	Weighted- Average Grant Date Fair Value
Unvested balance at December 31, 2015	521	\$ 31.57
Granted	96	28.33
Vested	_	_
Forfeited	(9)	34.14
Unvested balance at June 30, 2016	608	\$ 31.04

During the six months ended June 30, 2016, the Company issued 83,980 RSUs to employees. These RSUs are subject to time-based vesting. As of June 30, 2016, there was approximately \$3.5 million of unrecognized compensation cost related to the time-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.28 years . 131,910 restricted stock units remained unvested and outstanding at June 30, 2016.

During the six months ended June 30, 2016, the Company issued 12,565 performance-based RSUs in addition to the 464,000 issued in 2015. The vesting of these performance-based RSUs is accelerated upon the occurrence of certain milestone events, but otherwise these RSUs vest in September 2019. As a result, when probable, compensation cost is recognized over the estimated period of achievement. If achievement is not considered probable the expense is recognized over the vesting period. As of June 30, 2016, there was approximately \$10.4 million of unrecognized compensation cost related to the performance-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 2.34 years. All 476,565 of these performance-based RSUs remained outstanding at June 30, 2016.

#### **Employee Stock Purchase Plan**

During the three months ended June 30, 2016 and 2015, the Company recorded \$0.1 million and \$0.1 million, respectively, and during the six months ended June 30, 2016 and 2015, the Company recorded \$0.1 million and \$0.1 million, respectively, of stock-based compensation expense related to the 2013 ESPP.

#### 17. Income Taxes

For the three and six months ended June 30, 2016 and 2015, the Company did not record a current or deferred income tax expense or benefit.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of June 30, 2016 and December 31, 2015.

The Company files income tax returns in the United States, and various state and foreign jurisdictions. The federal, state and foreign income tax returns are generally subject to tax examinations for the tax years ended December 31, 2012 through December 31, 2015. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state or foreign tax authorities to the extent utilized in a future period.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of June 30, 2016 and December 31, 2015, the Company did not have any significant uncertain tax positions.

# 18. Related Party Transactions

#### **Celgene Corporation**

In connection with prior arrangements, Celgene owned 12.9% and 12.3% of the Company's fully diluted equity as of June 30, 2016 and December 31, 2015, respectively. Refer to Note 15 for additional information regarding this collaboration arrangement.

During the three and six months ended June 30, 2016 and 2015, all revenue recognized by the Company was recognized under the Celgene collaboration arrangement and, as of June 30, 2016, the Company had \$4.5 million of deferred revenue related to the Celgene collaboration arrangement.

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

The following information should be read in conjunction with the unaudited condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015.

Certain matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "anticipate", "believe", "contemplate", "continue", "could", "estimate", "expect", "forecast", "goal", "intend", "may", "plan", "potential", "predict", "project", "should", "strategy", "target", "will", "would", "vision", or, in each case, the negative or other variations thereon or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- our ongoing and planned preclinical studies and clinical trials;
- clinical trial data and the timing of results of our ongoing clinical trials;
- our plans to develop and commercialize dalantercept and ACE-083, and our and Celgene's plans to develop and commercialize luspatercept and sotatercept;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;
- the timing of, and our and Celgene's ability to, obtain and maintain regulatory approvals for our therapeutic candidates;
- the rate and degree of market acceptance and clinical utility of any approved therapeutic candidate, particularly in specific patient populations;
- our ability to quickly and efficiently identify and develop therapeutic candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, prospects, growth and strategies.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and industry changes and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and events in the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statements, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the section "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, press releases, and our website.

You should read the following discussion and analysis of financial condition and results of operations together with Part I Item 1 "Financial Statements" and related notes included elsewhere in this Quarterly Report on Form 10-Q.

#### Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of highly innovative therapeutics to treat serious and rare diseases. Our research focuses on key natural regulators of cellular growth and repair, particularly the Transforming Growth Factor-Beta, or TGF-beta, protein superfamily. We are a leading

company in discovering and developing therapeutic candidates that regulate cellular growth and repair. By combining our discovery and development expertise, including our proprietary knowledge of the TGF-beta superfamily, and our internal protein engineering and manufacturing capabilities, we have built a highly productive discovery and development platform that has generated innovative therapeutic candidates with novel mechanisms of action. These differentiated therapeutic candidates have the potential to significantly improve clinical outcomes for patients across many fields of medicine, and we have focused our discovery and development efforts on treatments for cancer and rare diseases.

We have four internally discovered therapeutic candidates that are currently in clinical trials: luspatercept, sotatercept, dalantercept and ACE-083.

Luspatercept, our lead program, and sotatercept, are partnered with Celgene Corporation, or Celgene. Luspatercept is designed to promote red blood cell production through a novel mechanism, and we are developing luspatercept with Celgene to treat anemia and associated complications in myelodysplastic syndromes (MDS) and beta-thalassemia. In 2015, Celgene initiated two Phase 3 clinical trials for luspatercept for the treatment of MDS and beta-thalassemia. We and Celgene are developing sotatercept to treat patients with chronic kidney disease. Sotatercept has the potential to treat several complications of chronic kidney disease including mineral-bone disorder, vascular calcification and anemia. Celgene is responsible for paying 100% of the development costs for all clinical trials for luspatercept and sotatercept, including our ongoing earlier stage clinical trials for these therapeutic candidates. We may receive up to an additional \$545.0 million of potential development, regulatory and commercial milestone payments and, if these therapeutic candidates are commercialized, we will receive a royalty on net sales in the low-to-mid 20% range. We will co-promote luspatercept and sotatercept, if approved, in North America for which our commercialization costs will be entirely funded by Celgene.

We wholly own dalantercept and ACE-083, and we are independently developing these therapeutic candidates. We are currently evaluating dalantercept in a Phase 2 clinical trial for the treatment of patients with renal cell carcinoma. ACE-083 is designed for the treatment of focal muscle disorders, such as facioscapulohumeral dystrophy, and we have completed a Phase 1 clinical trial with ACE-083 in healthy volunteers. We have reported data from the Phase 1 clinical trial of ACE-083 showing marked increases in the volume of muscles treated with ACE-083, and we intend to advance ACE-083 into a Phase 2 clinical trial in patients with facioscapulohumeral dystrophy.

In addition to our clinical programs, we are conducting research to identify new therapeutic candidates to bring forward into clinical trials. To this end, in 2015 we implemented a new platform technology, IntelliTrap ™, which is accelerating our discovery efforts. We have nominated an IntelliTrap ™ molecule, ACE-2494, as a candidate for clinical development and will initiate investigations new drug-enabling activities in 2016. ACE-2494 is designed to treat systemic muscle disorders.

As of June 30, 2016, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$337.3 million from public investors, \$96.2 million in equity investments from our collaboration partners and \$255.0 million in upfront payments, milestones, and net research and development payments from our collaboration partners.

We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- conduct clinical trials for dalantercept and ACE-083;
- continue our preclinical studies and potential clinical development efforts of our existing preclinical therapeutic candidates;
- continue research activities for the discovery of new therapeutic candidates:
- manufacture therapeutic candidates for our preclinical studies and clinical trials;
- seek regulatory approval for our therapeutic candidates; and
- operate as a public company.

We will not generate revenue from product sales unless and until we or a partner successfully complete development and obtain regulatory approval for one or more of our therapeutic candidates. We expect that this will take a number of years and is subject to significant uncertainty. All current and future development and commercialization costs for sotatercept and luspatercept are paid by Celgene. If we obtain regulatory approval for dalantercept, ACE-083 or any future therapeutic candidate, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such costs are not paid by future partners. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential additional collaborations. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all. If we fail to raise capital or

enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our therapeutic candidates.

Our ability to generate product revenue and become profitable depends upon our and our partners' ability to successfully commercialize products. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our therapeutic candidates and potentially begin to commercialize any approved products. For a description of the numerous risks and uncertainties associated with product development, see "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015.

#### **Financial Operations Overview**

#### Revenue

#### Collaboration Revenue

We have not generated any revenue from the sale of products. Our revenue to date has been predominantly derived from collaboration revenue, which includes license and milestone revenues and cost sharing revenue, generated through collaboration and license agreements with partners for the development and commercialization of our therapeutic candidates. Cost sharing revenue represents amounts reimbursed by our collaboration partners for expenses incurred by us for research and development activities and, potentially, co-promotion activities, under our collaboration agreements. Cost sharing revenue is recognized in the period that the related activities are performed. To the extent that we reimburse collaborators for costs incurred in connection with activities performed by them, we record these costs as a reduction of cost-sharing revenue.

#### **Costs and Expenses**

# Research and Development Expenses

Research and development expenses consist primarily of costs directly incurred by us for the development of our therapeutic candidates, which include:

- direct employee-related expenses, including salaries, benefits, travel and stock-based compensation expense of our research and development personnel;
- expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that will conduct our clinical trials;
- the cost of acquiring and manufacturing preclinical and clinical study materials and developing manufacturing processes;
- · allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, insurance and other supplies;
- · expenses associated with obtaining and maintaining patents; and
- costs associated with preclinical activities and regulatory compliance.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our therapeutic candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our therapeutic candidates for which we or any partner obtain regulatory approval. We or our partners may never succeed in achieving regulatory approval for any of our therapeutic candidates. The duration, costs and timing of clinical trials and development of our therapeutic candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a therapeutic candidate could mean a significant change in the costs and timing associated with the development of that therapeutic candidate. For example, if the U.S. Food and Drug Administration, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of our therapeutic candidates, or if we experience significant delays in the enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2016, we have incurred \$428.8 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of our TGF-beta platform therapeutic candidates, the discovery and development of preclinical therapeutic candidates, and the development of sotatercept, luspatercept and ACE-083. As of January 1, 2013, expenses associated with sotatercept and luspatercept are reimbursed 100% by Celgene. These reimbursements are recorded as revenue. We are expensing the costs of eight Phase 2 clinical trials for luspatercept, dalantercept and ACE-083, of which the four for luspatercept are reimbursed by Celgene, and we are also expensing the costs of a Phase 1 clinical trial for ACE-083. With respect to the luspatercept Phase 3 clinical trials directly conducted by Celgene, we do not incur and are not reimbursed for expenses related to these development activities.

We manage certain activities such as clinical trial operations, manufacture of therapeutic candidates, and preclinical animal toxicology studies through third-party CROs. The only costs we track by each therapeutic candidate are external costs such as services provided to us by CROs, manufacturing of preclinical and clinical drug product, and other outsourced research and development expenses. We do not assign or allocate to individual development programs internal costs such as salaries and benefits, facilities costs, lab supplies and the costs of preclinical research and studies. Our external research and development expenses during the three and six months ended June 30, 2016 and 2015 are as follows:

	 Three Months Ended Six Months June 30, June				
(in thousands)	2016		2015	2016	2015
Luspatercept(1)	\$ 1,703	\$	2,686	3,319	5,230
Dalantercept	2,133		1,847	4,087	4,092
ACE-083	737		725	1,614	1,767
Total direct research and development expenses	4,573		5,258	9,020	11,089
Other expenses(2)	11,565		8,892	23,370	17,841
Total research and development expenses	\$ 16,138	\$	14,150	\$32,390	\$28,930

- (1) As of January 1, 2013, expenses associated with sotatercept and luspatercept are reimbursed 100% by Celgene. These reimbursements are recorded as revenue and are presented as cost-sharing, net. In the periods presented, Celgene conducted most of the development activities for sotatercept, and we do not incur and are not reimbursed for expenses related to development activities directly conducted by Celgene.
- (2) Other expenses include unallocated employee and contractor-related expenses, facility expenses, lab supplies, miscellaneous expenses and expenses associated with preclinical programs.

#### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions and other general and administrative expenses including directors' fees and professional fees for accounting and legal services.

Since the completion of our initial public offering in September 2013, we have experienced increased expenses related to audit, legal, regulatory and taxrelated services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and
officer insurance premiums, and investor relations costs associated with being a public company. We anticipate that our general and administrative expenses will
increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our therapeutic
candidates. Additionally, if and when we believe regulatory approval of a therapeutic candidate appears likely, to the extent that we are undertaking
commercialization of such therapeutic candidate ourselves, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial
operations.

# Other (Expense) Income, Net

Other (expense) income, net consists primarily of the re-measurement gain or loss associated with the change in the fair value of our common stock warrant liabilities and interest income earned on cash, cash equivalents and investments.

To estimate the fair value of our liability classified warrants, we use either the Monte Carlo simulation framework, which incorporates future financing events over the remaining life of the warrants to purchase common stock, or for certain re-measurement dates, due to the warrants being deeply in the money, the Black-Scholes option pricing model. We base the estimates in the pricing models, in part, on subjective assumptions, including stock price volatility, risk-free interest rate, dividend yield, and the fair value of the preferred stock or common stock underlying the warrants. The Monte Carlo simulation framework was used at June 30, 2016.

#### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and stock-based compensation. We also utilize significant estimates and assumptions in determining the fair value of our liability-classified warrants to purchase common stock. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies since December 31, 2015. For further information on our critical and other significant accounting policies, see the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015.

#### **Results of Operations**

#### Comparison of the Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,		Increase		
(in thousands)		2016	2015	(Decrease)	
Revenue:					
Collaboration revenue:					
License and milestone	\$	135	\$ 431	\$	(296)
Cost-sharing, net		3,060	5,286		(2,226)
Total revenue		3,195	5,717		(2,522)
Costs and expenses:					
Research and development		16,138	14,150		1,988
General and administrative		6,712	4,661		2,051
Total costs and expenses		22,850	18,811		4,039
Loss from operations		(19,655)	(13,094)		(6,561)
Other (expense) income, net		(2,361)	2,711		(5,072)
Net loss	\$	(22,016)	\$ (10,383)	\$	(11,633)

**Revenue.** We recognized revenue of \$3.2 million in the three months ended June 30, 2016, compared to \$5.7 million in the same period in 2015. All of the revenue in both periods was derived from the Celgene agreements. This \$2.5 million decrease was primarily due to a decrease in cost sharing revenue of \$2.2 million due to lower expenses for luspatercept clinical trials and toxicology studies and manufacturing bulk drug substance during 2015, and a decrease in Celgene deferred revenue of \$0.3 million as we complete our deliverables under the Celgene agreements.

**Research and Development Expenses.** Research and development expenses were \$16.1 million in the three months ended June 30, 2016, compared to \$14.2 million in the same period in 2015. This \$1.9 million increase was primarily due to an increase in personnel expenses totaling \$1.9 million, which includes an increase in stock-based compensation expense of \$0.8 million. Other increases include miscellaneous research and drug supply expenses of \$0.9 million. These increases were partially offset by a decrease in clinical trial and toxicology expenses totaling \$0.9 million.

General and Administrative Expenses. General and administrative expenses were \$6.7 million in the three months ended June 30, 2016, compared to \$4.7 million for the same period in 2015. This \$2.0 million increase was primarily due to an increase in personnel expenses of 1.5 million, which includes an increase in stock-based compensation expense of \$1.1 million, and an increase in professional fees of \$0.5 million.

Other (Expense) Income, Net. Other expense, net was \$2.4 million in the three months ended June 30, 2016, compared to other income, net of \$2.7 million for the same period in 2015. This \$5.1 million change was primarily due to a \$5.4 million increase in expense due to marking the common warrant liability to market in each period, offset by a \$0.3 million increase in interest income in the three months ended June 30, 2016 due to changes in the total investments held in each period and the mix of investments.

#### Comparison of the Six Months Ended June 30, 2016 and 2015

	Six Months Ended June 30,			Increase		
(in thousands)		2016		2015	(Decrease)	
Revenue:						
Collaboration revenue:						
License and milestone	\$	15,279	\$	803	\$	14,476
Cost-sharing, net		6,117		9,336		(3,219)
Total revenue		21,396		10,139		11,257
Costs and expenses:						
Research and development		32,390		28,930		3,460
General and administrative		12,618		9,360		3,258
Total costs and expenses		45,008		38,290		6,718
Loss from operations		(23,612)		(28,151)		4,539
Other income, net		6,656		3,196		3,460
Net loss	\$	(16,956)	\$	(24,955)	\$	7,999

**Revenue.** We recognized revenue of \$21.4 million in the six months ended June 30, 2016, compared to \$10.1 million in the same period in 2015. All of the revenue in both periods was derived from the Celgene agreements. This \$11.3 million increase was primarily due to the receipt of a \$15.0 million milestone payment from Celgene for the initiation of a Phase 3 clinical trial with luspatercept, offset by a decrease in cost sharing revenue of \$3.2 million primarily due to lower expenses for luspatercept clinical trials and toxicology studies and manufacturing bulk drug substance during 2015, and a decrease in Celgene deferred revenue of \$0.5 million as we complete our deliverables under the Celgene agreements.

Research and Development Expenses. Research and development expenses were \$32.4 million in the six months ended June 30, 2016, compared to \$28.9 million in the same period in 2015. This \$3.5 million increase was primarily due to an increase in personnel expenses totaling \$3.2 million, which includes an increase in stock-based compensation expense of \$1.6 million. Other increases include licensing expense related to the achievement of our milestone totaling \$0.9 million and miscellaneous research and drug supply expenses of \$1.5 million. These increases were offset in part by a decrease in clinical trial and toxicology expenses totaling \$2.1 million.

General and Administrative Expenses. General and administrative expenses were \$12.6 million in the six months ended June 30, 2016, compared to \$9.4 million for the same period in 2015. This \$3.2 million increase was primarily due to an increase in personnel expenses of \$2.7 million, which includes an increase in stock-based compensation expense of \$2.0 million, as well as an increase in professional fees of \$0.5 million.

*Other Income*, *Net.* Other income, net was \$6.7 million in the six months ended June 30, 2016, compared to \$3.2 million for the same period in 2015. This \$3.5 million increase was primarily due to an increase of \$2.9 million in the effect of marking the common warrant liability to market in each period. Also, interest income in the three months ended June 30, 2016 increased by \$0.6 million due to changes in the total investments held in each period and the mix of investments.

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

We have incurred losses and cumulative negative cash flows from operations since our inception in June 2003, and as of June 30, 2016, we had an accumulated deficit of \$324.4 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of equity, debt financings or other sources, including potential additional collaborations.

As of June 30, 2016, our operations have been primarily funded by \$105.1 million in equity investments from venture investors, \$337.3 million from public investors, \$96.2 million in equity investments from our collaboration partners and \$255.0 million in upfront payments, milestones, and net research and development payments from our collaboration partners.

As of June 30, 2016, we had \$262.7 million in cash, cash equivalents and investments. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements into the second half of 2019.

#### **Cash Flows**

The following table sets forth the primary sources and uses of cash for each of the periods set forth below (in thousands):

	Six Months Ended June 30,			June 30,
(in thousands)	2016 2015		2015	
Net cash provided by (used in):				
Operating activities	\$	(14,933)	\$	(22,773)
Investing activities		(118,180)		(117,968)
Financing activities		142,325		2,437
Net increase (decrease) in cash and cash equivalents	\$	9,212	\$	(138,304)

#### **Operating Activities**

Net cash used in operating activities was \$14.9 million for the six months ended June 30, 2016 compared to \$22.8 million during the same period in 2015. The change was driven primarily by a decrease in net loss of \$8.0 million, which includes the receipt of a \$15.0 million milestone payment during the six months ended June 30, 2016. Also included in the change in net loss is an increase in operating expenses of \$6.7 million during the six months ended June 30, 2016. Non-cash changes in the six months ended June 30, 2016 compared to the same period in 2015 include a \$2.9 million increase in the gain associated with marking the common warrants to market, a \$3.6 million increase in stock-based compensation expense, a \$0.3 million decrease for net amortization of premium paid for investments, a \$0.1 million increase in depreciation and amortization expense, and a \$1.2 million net decrease in operating assets and liabilities.

#### **Investing Activities**

Net cash used in investing activities was \$118.2 million for the six months ended June 30, 2016 compared to \$118.0 million for the six months ended June 30, 2015. Our net cash used in investing activities during the six months ended June 30, 2016 was due to us investing the proceeds from our public offering in January 2016, in which we raised net proceeds of \$140.3 million, compared to during the six months ended June 30, 2015, which was due to the implementation of our investment policy pursuant to which we began to invest in marketable securities.

#### Financing Activities

Net cash provided by financing activities was \$142.3 million for the six months ended June 30, 2016 compared to \$2.4 million for the same period in 2015. The increase is due to the net proceeds from our January 2016 public offering of \$140.3 million, partially offset by a decrease in the proceeds from the exercise of stock options and warrants.

# **Operating Capital Requirements**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We will not generate revenue from product sales unless and until we or our partners obtain regulatory approval of and commercialize one of our current or future therapeutic candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek and obtain regulatory approvals for, dalantercept, ACE-083 and any future therapeutic candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development of therapeutic candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Since the closing of our initial public offering, we have incurred, and expect to continue to incur, additional costs associated with operating as a public company. We anticipate that we will need additional funding in connection with our continuing operations.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements into the second half of 2019. However, we will require additional capital for the further development of our existing therapeutic candidates and may also need to raise additional funds sooner to pursue other development activities related to additional therapeutic candidates.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to fund our operations through a combination of equity offerings, debt financings or other sources, including potential additional collaborations. Additional capital may not be available on favorable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our therapeutic candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations, and these securities

may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may not be able to enter into new collaboration arrangements for any of our proprietary therapeutic candidates. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the achievement of milestones under our agreement with Celgene;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our therapeutic candidates and potential therapeutic candidates;
- the number and characteristics of therapeutic candidates that we pursue;
- the progress, costs and results of our clinical trials;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the costs and timing of procuring clinical and commercial supplies of our therapeutic candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the costs involved in defending and prosecuting litigation regarding in-licensed intellectual property.

#### Net Operating Loss (NOL) Carryforwards

We had deferred tax assets of approximately \$109.8 million as of December 31, 2015, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal and state tax net operating loss, or NOL, carryforwards and research and development tax credit carryforwards. As of December 31, 2015, we had federal NOL carryforwards of approximately \$276.1 million and state NOL carryforwards of \$229.8 million available to reduce future taxable income, if any. These federal and state NOL carryforwards expire at various times through 2035. In general, if we experience a greater than 50 percent aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state laws. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. If we experience a Section 382 ownership change in connection with our public offerings or as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carryforwards may be limited or lost. For additional information about our taxes, see Note 13 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

During the three months ended June 30, 2016, there were no material changes to our contractual obligations and commitments described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2015.

#### **Recent Accounting Pronouncements**

For information on recent accounting pronouncements, see Recently Issued and Adopted Accounting Standards in the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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

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

#### Item 3. Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. As of June 30, 2016 and December 31, 2015, we had cash, cash equivalents and investments of \$262.7 million and \$136.0 million, respectively. Our cash equivalents are invested primarily in bank deposits and money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. We do not enter into financial instruments for trading or speculative purposes. Due to the duration of our investment portfolio and the low risk profile of our investments, we do not believe an immediate 100 basis point change in interest rates would have a material effect on the fair market value of our portfolio. We have the ability to hold our investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

We contract with CROs and manufacturers internationally. Transactions with these providers are predominantly settled in U.S. dollars and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

#### **Item 4. Controls and Procedures**

#### Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, or the Exchange Act, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2016, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2016, the design and operation of our disclosure controls and procedures were effective.

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

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended June 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

# **Item 1. Legal Proceedings**

While we are not currently a party to any material legal proceedings, we could become subject to legal proceedings in the ordinary course of business. We do not expect any such potential items to have a significant impact on our financial position.

# Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

# Item 6. Exhibits

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

#### **SIGNATURES**

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

# ACCELERON PHARMA INC.

Date: August 4, 2016 By: /s/ JOHN L. KNOPF, PH.D.

John L. Knopf, Ph.D.

Chief Executive Officer and President

Date: August 4, 2016 By: /s/ KEVIN F. MCLAUGHLIN

Kevin F. McLaughlin

 ${\it Senior\ Vice\ President,\ Chief\ Financial\ Officer\ and\ Treasurer}$ 

#### **EXHIBIT INDEX**

Exhibit Number	Description of Exhibit
10.1+	Collaboration, License and Option Agreement between Acceleron Pharma Inc. and Celgene Corporation, dated February 20, 2008, and amended August 2, 2011.
10.2+	Amended and Restated License Agreement between Acceleron Pharma Inc. and Ludwig Institute for Cancer Research Ltd., dated August 6, 2010 (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (333-190417), filed on August 7, 2013).
10.3+	Exclusive License Agreement between Beth Israel Deaconess Medical Center and Acceleron Pharma Inc., dated June 21, 2012.
10.4*	Acceleron Pharma Inc. Short-Term Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (001-36065), filed on June 6, 2016).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer 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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

<sup>+</sup> Confidential treatment has been granted by, or is being requested from, the Securities and Exchange Commission as to certain portions of this exhibit (indicated by asterisks), which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, as applicable.

<sup>\*</sup> Management contract or compensatory plan or arrangement.

# COLLABORATION, LICENSE AND OPTION AGREEMENT

by and between

ACCELERON PHARMA, INC.

and

**CELGENE CORPORATION** 

as amended on August 2, 2011

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### COLLABORATION, LICENSE AND OPTION AGREEMENT

This Collaboration, License and Option Agreement (this "Agreement") dated the 20th day of February, 2008 (the "Execution Date") is by and between Acceleron Pharma, Inc., a Delaware corporation having its principal office at 149 Sidney Street, Cambridge, MA 02139 ("Acceleron"), and Celgene Corporation, a Delaware corporation having its principal office at 86 Morris Avenue, Summit, NJ 07901 ("Celgene"). Acceleron and Celgene may each be referred to herein individually as a "Party" and collectively as the "Parties."

This First Amendment to the Collaboration, License and Option Agreement (this "Amendment") is entered into as of August 2, 2011 (the "Effective Date"), by and between Acceleron Pharma, Inc., a Delaware corporation having its principal office at 128 Sidney Street, Cambridge, MA 02139 ("Acceleron"), and Celgene Corporation, a Delaware corporation having its principal office at 86 Morris Avenue, Summit, NJ 07901 ("Celgene"). Acceleron and Celgene may each be referred to herein individually as a "Party" and collectively as the "Parties."

#### **RECITALS**

- A. Celgene and Acceleron are parties that certain Collaboration, License and Option Agreement dated February 20, 2008 (the " **Original Agreement**"), pursuant to which, among other things, Celgene and Acceleron agreed to collaborate in the investigation and development of certain protein-based product candidates incorporating ActRIIA for the treatment, prevention, or modulation of diseases and conditions in humans.
- B. The Parties desire to amend certain terms of the Original Agreement.

#### INTRODUCTION

WHEREAS, Acceleron owns or otherwise controls certain intellectual property relating to ActRIIA and antibodies targeting [\* \* \*], [\* \* \*], and [\* \* \*] (each as defined below), including compositions, methods of screening and methods of treatment;

WHEREAS, Celgene is in the business of discovering, developing and commercializing innovative therapies designed to treat cancer and immunological diseases through regulation of genomic and proteomic targets;

WHEREAS, Acceleron and Celgene are interested in collaborating, on the terms and conditions set forth herein, in the investigation and development of certain protein-based product candidates incorporating ActRIIA for the treatment, prevention, or modulation of diseases and conditions in humans; and

WHEREAS, Acceleron and Celgene are interested in entering into an option arrangement regarding rights to collaborate in the investigation and development of certain product candidates

incorporating antibodies targeting [\* \* \*], [\* \* \*], and [\* \* \*] for the treatment, prevention, or modulation of diseases and conditions in humans;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

#### Article 1

#### **DEFINITIONS**

Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or Schedule or Exhibit to this Agreement, unless another agreement is specified, (b) the word "including" will be construed as "including without limitation," (c) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulations, in each case, as amended or otherwise modified from time to time, (d) words in the singular or plural form include the plural and singular form, respectively, (e) words of any gender include each other gender, (f) "or" is disjunctive but not necessarily exclusive, (g) the word "will" shall be construed to have the same meaning and effect as the word "shall," (h) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified, and (i) references to a particular person include such person's successors and assigns to the extent not prohibited by this Agreement.

When used in this Agreement, each of the following terms shall have the meanings set forth in this <u>Article 1</u>:

- 1.1 "Acceleron Collaboration IP" means any and all Collaboration IP created, conceived or reduced to practice, and, in the case of patentable Collaboration IP, Invented, solely by Acceleron, its Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; <u>provided</u>, <u>however</u>, that Acceleron Collaboration IP shall not include any Collaboration IP that is Celgene Collaboration IP or Joint Collaboration IP.
- 1.2 "Acceleron Development Activities" means all Development activities, including preclinical pharmacology studies, preclinical safety studies, Phase 1 Clinical Trials, initial Phase 2A Clinical Trials, and formulation development for Clinical Supply for such Clinical Trials, undertaken by Acceleron pursuant to this Agreement for the purpose of obtaining Regulatory Approval within North America and Europe.
- 1.3 "Acceleron Improvements" means any and all Improvements to the Acceleron Technology or the Joint Technology created, conceived or reduced to practice, and, in the case of patentable Improvements, Invented, solely by Acceleron, its Affiliates, agents, or by Third Parties acting on their behalf, while performing activities under this Agreement; <u>provided</u>, <u>however</u>, that Acceleron Improvements shall not include any Improvement that is a Celegne Improvement or Joint Improvement.

- 1.4 "Acceleron Know-How" means any Know-How (other than Acceleron Improvements and Acceleron Collaboration IP) that is either Controlled by Acceleron on the Effective Date or comes within Acceleron's Control during the Agreement Term and is necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field. For avoidance of doubt, to the extent that antibodies that bind to [\* \* \*] or receptors to which [\* \* \*] binds are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field, then, to the extent Controlled by Acceleron on the Effective Date or during the Agreement Term, the composition of such antibodies are included in the Acceleron Know-How.
- 1.5 "Acceleron Patent Rights" means (a) the United States and foreign patents and patent applications listed in Schedule 1.5 and, effective upon the dates and pursuant to the terms set forth in Section 7.2, the [\*\*\*] Antibody Patent Rights, [\*\*\*] Antibody Patent Rights and [\*\*\*] Antibody Patent Rights, as applicable, (b) any Patent Rights arising from those patents and patent applications during the Agreement Term, (c) any Patent Rights resulting from Acceleron Improvements or Acceleron Collaboration IP, and (d) any other Patent Rights Controlled by Acceleron as of the Effective Date or during the Agreement Term (but, in the case of Third Party Intellectual Property Controlled by Acceleron during the Agreement Term, subject to Section 5.6.3(c)); all of the above (a) through (d) solely to the extent that such Patent Rights claim the manufacture or use of a Licensed Compound or a Licensed Product, claim a composition of matter of or including a Licensed Compound or a Licensed Product, or are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field. For the avoidance of doubt, any Patent Rights that claim the use of a Licensed Compound or Licensed Product in combination with another product (including the use of a Licensed Compound or Licensed Product as part of a Combination Product) shall be included within "Acceleron Patent Rights" (if otherwise within this definition); provided that such inclusion shall not cause "Acceleron Patent Rights" to include any other Patent Rights that claim such other product or the use or manufacture of such other product (or the other active component of a Combination Product) that is not a Licensed Compound or Licensed Product.
- 1.6 "Acceleron Technology" means Acceleron Patent Rights, Acceleron Know-How, Acceleron Improvements, and Acceleron Collaboration IP.
- 1.7 "**ActRIIA**" means (a) any fusion protein containing at least [\* \* \*] consecutive amino acids from the extracellular portion of human ActRIIA or a mammalian ortholog thereof, linked to an Fc region of an immunoglobulin, (b) any dimers or multimers of (a), and (c) any nucleic acid encoding a protein of (a) or (b). For clarity, and without limiting the foregoing, the term "ActRIIA" specifically includes the fusion protein identified as ACE-011 and the protein having the sequence of [\* \* \*].
- 1.8 "ActRIIB" means (a) any fusion protein containing at least [\* \* \*] consecutive amino acids from the extracellular portion of human ActRIIB or a mammalian ortholog thereof, linked to an Fc region of an immunoglobulin, (b) any dimers or multimers of (a), and (c) any nucleic acid encoding a protein of (a) or (b). For clarity, and without limiting the foregoing, the term

"ActRIIB" specifically includes the fusion protein identified as [\* \* \*] and the protein having the sequence of [\* \* \*].

- 1.9 "[\*\*\*]" means (i) the protein having the sequence set forth in GenBank Entry [\*\*\*] and dimers, multimers and fragments thereof and (ii) mammalian orthologs of (i), and dimers, multimers and fragments thereof.
- 1.10 "[\*\*\*] **Antibody**" means any antibody that binds to [\*\*\*] with a dissociation constant (K  $_D$ ) of 500 picomolar or less. The terms "[\*\*\*] **Antibody**" and "[\*\*\*] **Antibody**" may each include antibodies that bind to both [\*\*\*] and [\*\*\*].
- 1.11 "[\*\*\*] **Antibody Patent Rights**" means the United States and foreign patents and patent applications listed in <u>Schedule</u> 1.11.
- 1.12 "[\*\*\*]" means (i) the protein having the sequence set forth in GenBank Entry [\*\*\*] and dimers, multimers and fragments thereof and (ii) mammalian orthologs of (i), and dimers, multimers and fragments thereof.
- 1.13 "[\*\*\*] **Antibody**" means any antibody that binds to [\*\*\*] with a dissociation constant (K  $_D$ ) of 500 picomolar or less. The terms "[\*\*\*] **Antibody**" and "[\*\*\*] **Antibody**" may each include antibodies that bind to both [\*\*\*] and [\*\*\*].
- 1.14 "[\*\*\*] **Antibody Patent Rights**" means the United States and foreign patents and patent applications listed in <u>Schedule</u> 1.14.
- 1.15 "Affiliate" means, with respect to a subject entity, another entity that, directly or indirectly, controls, is controlled by, or is under common control with such subject entity, for so long as such control exists. For purposes of this definition only, "control" means ownership, directly or indirectly through one or more Affiliates, of at least fifty percent (50%) of the equity securities of the entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, in the election of the corresponding managing authority, or in the case of a partnership, the status as a general partner) or any other arrangement whereby an entity controls or has the right to control the board of directors or equivalent governing body or management of a corporation or other entity.
- 1.16 "**Agreement Term**" means the period commencing on the Effective Date and ending upon the termination of this Agreement with respect to both North America and the Territory outside North America, in accordance with <u>Section 11.1</u>.
- 1.17 "**Applicable Law**" means the applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- 1.18 "Bankruptcy Code" means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

- 1.19 "[\*\*\*]" means (i) the protein having the sequence set forth in GenBank Entry [\*\*\*] and dimers, multimers and fragments thereof and (ii) mammalian orthologs of (i), and dimers, multimers and fragments thereof.
- 1.20 "[\*\*\*] **Antibody**" means any antibody that binds to [\*\*\*] with a dissociation constant (K<sub>D</sub>) of 500 picomolar or less.
- 1.21 "[\*\*\*] **Antibody Patent Rights**" means the United States and foreign patents and patent applications listed in <u>Schedule</u> 1.21.
- 1.22 "Business Day" means a day on which banking institutions in Boston, Massachusetts and Trenton, New Jersey are open for business.
- 1.23 "Cancer-Related Bone Loss" [Definition deleted]
- 1.24 "Celgene Collaboration IP" means any and all Collaboration IP created, conceived or reduced to practice, and, in the case of patentable Collaboration IP, Invented, solely by Celgene, its Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; provided, however, that Celgene Collaboration IP shall not include any Collaboration IP that is Acceleron Collaboration IP or Joint Collaboration IP.
- 1.25 "Celgene Development Activities" means (i) all Development activities, including Phase 2B Clinical Trials, Phase 3 Clinical Trials, any formulation development for Licensed Compounds or Licensed Products taking place after the end of Phase 2A Clinical Trials, and any other Development activities taking place after the end of Phase 2A Clinical Trials, undertaken by Celgene pursuant to this Agreement for the purpose of obtaining Regulatory Approval in North America and Europe, and (ii) all Development activities, including all Clinical Trials and other Development activities undertaken by Celgene pursuant to this Agreement for the purpose of obtaining Regulatory Approvals outside North America and Europe.
- 1.26 "Celgene Improvements" means (a) any and all Improvements to the Joint Technology created, conceived or reduced to practice, and, in the case of patentable Improvements, Invented, solely by Celgene, its Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; and (b) any and all Improvements to the Celgene Technology created, conceived or reduced to practice, and, in the case of patentable Improvements, Invented, solely by either Party, its Affiliates, agents or by Third Parties acting on their behalf or jointly by the Parties, their respective Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; provided, however, that Celgene Improvements shall not include any Improvement that is an Acceleron Improvement or Joint Improvement.
- 1.27 "Celgene Know-How" means any Know-How (other than Celgene Improvements and Celgene Collaboration IP) that is either Controlled by Celgene on the Effective Date or comes within Celgene's Control during the Agreement Term that Celgene, in its sole discretion, actually uses and is necessary to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field.

- 1.28 "Celgene Patent Rights" means (a) any Patent Rights resulting from Celgene Improvements or Celgene Collaboration IP and (b) any other Patent Rights Controlled by Celgene as of the Effective Date or during the Agreement Term, other than the Acceleron Patent Rights, that Celgene, in its sole discretion, actually uses and are necessary to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field; for each of (a) and (b) above, solely to the extent that such Patent Rights claim the manufacture or use of a Licensed Compound or a composition of matter of or including a Licensed Compound. For the avoidance of doubt, any Patent Rights that claim the use of a Licensed Compound or Licensed Product in combination with another product (including the use of a Licensed Compound or Licensed Product as part of a Combination Product) shall be included within "Celgene Patent Rights" (if otherwise within this definition); provided that such inclusion shall not cause "Celgene Patent Rights" to include any other Patent Rights that claim such other product or the use or manufacture of such other product (or the other active component of a Combination Product) that is not a Licensed Compound or Licensed Product.
- 1.29 "Celgene Technology" means Celgene Know-How, Celgene Patent Rights, Celgene Improvements, and Celgene Collaboration IP.
- 1.30 "Change of Control" means, with respect to a Party, (i) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (ii) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (iii) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates.
- 1.31 "Clinical Supplies" means supplies of Licensed Compound and Licensed Product Manufactured by or on behalf of Celgene or Acceleron in compliance with GLP and GMP and meeting the FDA Guidance for Biologics License Applications, Product License Applications/Establishment License Applications, New Drug Applications, and supplements and amendments to those applications to Center for Biologics Evaluation and Research (CBER) and EMEA guidances, in each case, if required given the intended use, and ready to be used for the conduct of pre-clinical or human clinical trials of such Licensed Product in the Field.
- 1.32 "Clinical Trial" means a study in humans that is conducted in accordance with GCP and is designed to generate data in support of an NDA.
- 1.33 "Closing" means, subject to the satisfaction or waiver of the conditions set forth in <u>Section 10.4</u> of this Agreement, the closing of the transactions contemplated by this Agreement.
- 1.34 "Collaboration IP" means (a) any and all ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable or copyrightable, in each case, that is not an improvement to then-existing Acceleron Technology, Celgene Technology, or Joint

Technology and is developed by either Party, its Affiliates or Third Parties acting on their behalf while performing activities under this Agreement, and (b) all Patent Rights and other intellectual property rights in any of the foregoing.

- 1.35 "Combination Product" means any product that comprises a Licensed Compound or Licensed Product sold in conjunction with another active component so as to be a combination product (whether packaged together or in the same therapeutic formulation).
- 1.36 "Commercial Supplies" means supplies of Licensed Product in final packaged form Manufactured by or on behalf of Celgene in compliance with GMP and meeting FDA Guidance for Biologics License Applications, Product License Applications/Establishment License Applications, New Drug Applications, and supplements and amendments to those applications to Center for Biologics Evaluation and Research (CBER) and EMEA guidances, in each case, if required given the intended use, and ready to be offered for commercial sale by Acceleron or Commercialized by Celgene, or their respective Affiliates or Sublicensees, for use in the Field in the Territory.
- 1.37 "Commercialization" means any and all activities using, constituting, importing, marketing, distributing, offering for sale and selling Licensed Products in the Field in the Territory following or in expectation of receipt of Regulatory Approval (but excluding Development) and shall include Promotion as well as activities required to fulfill ongoing regulatory obligations, including adverse event reporting but excluding any Post-Approval Clinical Trials. When used as a verb, "Commercialize" means to engage in Commercialization.
- 1.38 "Commercially Reasonable Efforts" means, for each Party, the carrying out of obligations in a diligent and sustained manner using such effort and employing such resources as would normally be exerted or employed by a similarly-situated biopharmaceutical company for a product of similar market potential, and at a similar stage of its Development or product life, taking into consideration safety and efficacy, Development Costs, Operating Costs, the anticipated prescription label, the nature of the Licensed Product, the clinical setting in which it is expected to be used, competitiveness of the marketplace, regulatory environment, the patent or other proprietary position of the Licensed Product, and other conditions then prevailing. Commercially Reasonable Efforts shall be determined on a country-by-country basis; provided that, with respect to the co-Promotion obligations hereunder, such standard shall be based on an established biopharmaceutical company rather than a similarly-situated biopharmaceutical company.
- 1.39 "Confidential Information" means, with respect to each Party, proprietary data or information that belongs in whole or in part to such Party, its Affiliates or Sublicensees, and is disclosed to the other Party. Confidential Information of Celgene includes all Celgene Technology, the reports delivered by Celgene to Acceleron hereunder, all proprietary data and information of Celgene disclosed by Celgene at the Joint Development Committee or Joint Commercialization Committee meetings, and any information designated as Confidential Information of Celgene hereunder. Confidential Information of Acceleron includes Acceleron Technology, the reports delivered by Acceleron to Celgene hereunder, all proprietary data and information of Acceleron disclosed by Acceleron at the Joint Development Committee or Joint

Commercialization Committee meetings, and any information designated as Confidential Information of Acceleron hereunder. For clarity, information that is not otherwise Confidential Information of a Party hereunder shall not become Confidential Information by inclusion in a report delivered by such Party to the other Party. Confidential Information of both Parties includes Joint Technology and the terms and conditions of this Agreement. Confidential Information shall not include (as determined by competent documentation) information that:

- (a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party or its Affiliates by sources (other than the disclosing Party) rightfully in possession of the Confidential Information; or
- (b) either before or after the date of the disclosure to the receiving Party or its Affiliates becomes published or generally known to the public (including information known to the public through the sale of products in the ordinary course of business) through no fault or omission on the part of the receiving Party, its Affiliates or its Sublicensees; or
- (c) is independently developed by or for the receiving Party or its Affiliates without reference to or reliance upon the Confidential Information.
- 1.40 "Contract Year" means each calendar year during the Agreement Term; <u>provided</u>, <u>however</u>, that the first Contract Year shall begin on the Effective Date and end on December 31, 2008. Each Contract Year shall be divided into four (4) "Contract Ouarters" ending respectively on March 31, June 30, September 30 and December 31.
- 1.41 "Control" or "Controlled" means with respect to any (a) material, item of information, method, data or other Know-How or (b) Patent Rights or other intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access or a license as provided herein under such item or right without, in the case of such rights that are licensed from a Third Party, violating the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.
- 1.42 "Designated Countries" means the United States, member countries of the European Patent Convention, member countries of the Eurasian Patent Convention, Canada, Australia, Japan, South Korea, China, India and Brazil.
- 1.43 "Development" means all pre-clinical and clinical activities performed by or on behalf of either Party with respect to Licensed Compounds or Licensed Products in the Field in the Territory in an indication, or for the purpose of obtaining Regulatory Approval with respect to such indication, from the Effective Date until Regulatory Approval of such Licensed Compounds or Licensed Products is obtained for the indication being studied, including: (a) identification and early pre-clinical testing of Licensed Compounds; (b) toxicology, regulatory affairs, pre-clinical studies and clinical trials in accordance with the GLPs, GCPs and GMPs or other designated quality standards and Applicable Laws; and (c) all Manufacturing activities (until such time as Manufacturing of Commercial Supplies commences) relating to developing the ability to

Manufacture Licensed Product, including process and formulation development, process validation, manufacturing scale-up, manufacturing and analytical development, and quality assurance and quality control. When used as a verb, "**Develop**" means to engage in Development.

- 1.44 "**Development Costs**" means FTE Costs and other costs specifically identifiable or allocable to Development or regulatory activities for each Licensed Compound and Licensed Product and development of the Manufacturing process, as well as Manufacturing of Clinical Supplies, in each case, actually incurred by Celgene or Acceleron, or their respective Affiliates. Development Costs shall include:
  - (a) the costs associated with the production of Clinical Supplies (including \$[\*\*\*] of Acceleron costs for the 960 vials of Clinical Supplies produced by Acceleron prior to the Effective Date, which vials will be used in connection with Development pursuant hereto) for all Clinical Trials (including the costs associated with the transfer of Clinical Supplies to the site of use and including pre-Commercialization and post-Commercialization Clinical Trials), which costs of Clinical Supplies shall include such costs that would ordinarily be included as a "Cost of Goods Sold" under U.S. GAAP for a similar product, made on the basis of theoretical full capacity operation of the relevant facility, and shall be set forth in the Development Plan/Budget;
  - (b) the costs of studies on the toxicological, pharmacological, metabolic or clinical aspects of a Licensed Compound or Licensed Product necessary for the purpose of obtaining Regulatory Approval of a Licensed Compound or a Licensed Product:
  - (c) the costs of process and formulation development, process improvement and scale-up costs, validation costs, including qualification lots and costs for preparing, submitting, and reviewing or developing data or information for the purpose of submission to a governmental authority to obtain manufacturing or marketing approval of a Licensed Compound or a Licensed Product, in each case, to the extent that such costs and expenses are associated with Development activities;
  - (d) the costs associated with the transfer to a Third Party of, and implementation by a Third Party of, manufacturing technology necessary for the Development of a Licensed Product or Licensed Compound;
  - (e) costs of data management, statistical designs and studies, document preparation and other administration expenses associated with all Clinical Trials;
  - (f) Third Party Intellectual Property Costs associated with Development activities and the Manufacture of Clinical Supplies that are deemed Development Costs pursuant to Section 5.6.3(c);

- (g) Patent Procurement Costs to the extent provided in Section 8.2.4(b); and
- (h) capital expenditures incurred by Acceleron and approved pursuant to <u>Section 2.4.2</u>.

In determining Development Costs chargeable under this Agreement, the Parties shall use their respective project accounting systems (which must be consistent with the terms of this Agreement). The Parties shall consistently apply methodologies for calculating and allocating Development Costs based on their internal accounting systems (which must be consistent with the terms of this Agreement). Notwithstanding anything in this definition to the contrary, only those Development Costs that are contemplated by the Development Plan/Budget shall be chargeable by either Party as Development Costs with any cost overruns treated in the manner set forth in Section 5.5.4. Except to the extent included in cost of Clinical Supplies described in clause (a) above, expenses incurred by either Party for equipment, materials and supplies utilized in performing its activities under the Development Plan/Budget shall not be separately charged as Development Costs, except for those expenses incurred by either Party, as set forth in the Development Plan/Budget, in the purchase or making of equipment, materials or supplies (other than common laboratory supplies, e.g., pipettes, test tubes, petri dishes, reagents, and the like) that are to be used exclusively in connection with the performance of either Party's activities under the Development Plan/Budget (e.g., laboratory animals, placebo supplies, etc.), which expenses shall be charged as Development Costs at either Party's actual out-of-pocket expense incurred in purchasing or making such equipment, materials or supplies.

- 1.45 "Development Plan/Budget" means (a) the comprehensive plan for the Development of any Licensed Compound or Licensed Product for the purpose of obtaining Regulatory Approval in North America and Europe, including activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing NDAs in North America and Europe, and (b) a budget setting forth the internal and external resources and expenses, including the maximum costs to be incurred in a particular Contract Year, for such Development activities.
- 1.46 "**Effective Date**" means the earlier of: (i) the third Business Day after the expiration or termination of all applicable waiting periods under the HSR Act and the satisfaction of all the other conditions set forth in <u>Section 10.4</u> of this Agreement or (ii) the third Business Day after the joint determination (by certification from each Party to the other) that notification under the HSR Act is not required and the satisfaction of all the other conditions set forth in <u>Section 10.4</u> of this Agreement.
- 1.47 "**EMEA**" means the Regulatory Agency known as either the European Medicines Agency or the European Agency for the Evaluation of Medicinal Products, or a successor agency with responsibilities comparable to those of the European Medicines Agency or the European Agency for the Evaluation of Medicinal Products.
- 1.48 "**Europe**" means Switzerland and all countries in which the Development or Commercialization of a Licensed Compound or Licensed Product is regulated by the EMEA.

- 1.49 "**Executive Officers**" means the Chief Executive Officer of Celgene (or a designee of such Chief Executive Officer) and the Chief Executive Officer of Acceleron (or a designee of such Chief Executive Officer).
- 1.50 "FDA" means the United States Food and Drug Administration, or a successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.
- 1.51 "**Field**" means (i) the treatment, prevention, modulation, or diagnosis of any disease, disorder, or condition in humans, and (ii) any and all research uses and applications related to the Development, Manufacture and Commercialization of Licensed Compounds or Licensed Products.
- 1.52 "First Commercial Sale" means, with respect to a given Licensed Product in a country in the Territory, the first commercial sale in an arms' length transaction of such Licensed Product to a Third Party by or on behalf of a Party, its Affiliate or its Sublicensee in such country following receipt of applicable Regulatory Approval of such Licensed Product in such country.
- 1.53 "FTE Costs" means, for any Contract Quarter, the FTE Rate multiplied by the number of hours of service spent in that quarter by employees of Celgene or Acceleron, or their respective Affiliates, working directly on the Development or Commercialization of a Licensed Product.
- 1.54 "FTE Rate" means \$[\* \* \*] for employees of each of Acceleron and its Affiliates and Celgene and its Affiliates, which rate may be adjusted annually by each Party based on changes in the Consumer Price Index (as quoted by the U.S. Department of Labor, Bureau of Labor Statistics).
- 1.55 "GCP" means the international ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects. In the United States, GCP shall be based on Good Clinical Practices established through FDA guidances (including ICH E6).
- 1.56 "Generic Product" means a product on the market commercialized by a Third Party (excluding Sublicensees) that (a) is approved, under any then existing laws and regulations in the applicable country pertaining to approval of "generic" biologic products, as a "generic" version of a Licensed Product labeled for substantially similar indications as such Licensed Product; or (b) otherwise is recognized as a biosimilar or interchangeable biological product to the Licensed Product by the applicable Regulatory Authority.
- 1.57 "GLP" means the current Good Laboratory Practice (or similar standards) for the performance of laboratory activities for pharmaceutical products as are required by applicable Regulatory Authorities. In the United States, Good Laboratory Practices are established through FDA regulations (including 21 CFR Part 58), FDA guidances, FDA current review and inspection standards and current industry standards.

- 1.58 "GMP" means current Good Manufacturing Practices. In the United States, GMP shall be as defined under the rules and regulations of the FDA, as the same may be amended from time to time.
- 1.59 "HSR Act" means the Hart-Scott-Rodino Act of 1976, as amended.
- 1.60 "Improvements" means (a) any and all ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable or copyrightable, in each case, that is an improvement to then-existing Acceleron Technology, Celgene Technology, or Joint Technology and is developed by either Party, its Affiliates or Third Parties acting on their behalf while performing activities under this Agreement, and (b) all Patent Rights and other intellectual property rights in any of the foregoing.
- 1.61 "IND" means an Investigational New Drug Application, as defined in the Food Drug & Cosmetics Act, or similar application or submission that is required to be filed with any Regulatory Authority before beginning clinical testing of a Licensed Product in human subjects.
- 1.62 "Invented" means the act of invention by inventors, as determined in accordance with U.S. patent laws.
- 1.63 "Joint Collaboration IP" means any and all Collaboration IP created, conceived or reduced to practice, and, in the case of patentable Collaboration IP, Invented, jointly by Acceleron and Celgene, their respective Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; <u>provided</u>, <u>however</u>, that Joint Collaboration IP shall not include any Collaboration IP that is Acceleron Collaboration IP or Celgene Collaboration IP.
- 1.64 "Joint Improvements" means (a) any and all Improvements to the Acceleron Technology created, conceived or reduced to practice, and, in the case of patentable Improvements, Invented, solely by Celgene, its Affiliates, agents or by Third Parties acting on their behalf, while performing activities under this Agreement; and (b) any and all Improvements to the Acceleron Technology or Joint Technology created, conceived or reduced to practice, and, in the case of patentable Improvements, Invented, jointly by Acceleron and Celgene, their respective Affiliates, agents or Sublicensees or by Third Parties acting on their behalf, while performing activities under this Agreement; provided, however, that Joint Improvements shall not include any Improvement that is a Celgene Improvement or Acceleron Improvement.
- 1.65 "Joint Patent Rights" means any Patent Rights resulting from any Joint Improvements or Joint Collaboration IP.
- 1.66 "Joint Technology" means Joint Improvements, Joint Patent Rights, and Joint Collaboration IP.

- 1.67 "**Know-How**" means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, material, technology or other know-how, whether or not patentable or copyrightable. Know-How shall not include any Patent Rights with respect thereto.
- 1.68 "**Licensed Compound**" means ActRIIA, and, effective upon the dates and pursuant to the terms set forth in <u>Section 7.2</u>, any applicable Option Compound.
- 1.69 "Licensed Product" means any preparation in final form that contains a Licensed Compound.
- 1.70 "Major Market Countries" means the United States, the European Union, and Japan.
- 1.71 "Manufacturing" means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of Licensed Compounds or Licensed Products, including process and formulation development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, "Manufacture" means to engage in Manufacturing.
- 1.72 "Net Sales" means the aggregate gross invoice prices of all Licensed Products sold by Celgene, and its respective Affiliates and Sublicensees, to Third Parties anywhere within the Territory, including wholesale distributors, less deductions from such amounts calculated in accordance with U.S. GAAP so as to arrive at "net product sales" under U.S. GAAP, and further reduced by write-offs of accounts receivables or increased for collection of accounts that were previously written off.

The transfer of Licensed Products between or among Celgene, Acceleron and their Affiliates and Sublicensees shall be excluded from the computation of Net Sales.

Notwithstanding the foregoing, in the event a Licensed Compound or Licensed Product is sold as a Combination Product, Net Sales shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A/(A+B), where A is the gross invoice price of the Licensed Compound or Licensed Product if sold separately in a country and B is the gross invoice price of the other product(s) included in the Combination Product if sold separately in such country. In the event no such separate sales are made by Celgene, its Affiliates or Sublicensees in a country, Net Sales of the Combination Product shall be calculated in a manner to be negotiated and agreed upon by the Parties, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the respective cost of goods sold of the active components of such Combination Product.

1.73 "New Drug Application" or "NDA" means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314, a Biological License Application (BLA) pursuant to 21 C.F.R. § 601.2, or any equivalent or any corresponding application for Regulatory Approval (not

including pricing and reimbursement approval) in any country or regulatory jurisdiction other than the United States.

- 1.74 [Definition deleted]
- 1.75 "Non-Prosecuting Party" means, with respect to a particular Patent Right, the Party which is not the Prosecuting Party.
- 1.76 "North America" means the United States, including its territories and possessions, Canada and Mexico.
- 1.77 "North American and European Development Costs" means the subset of Development Costs for the purpose of obtaining Regulatory Approval in North America or Europe.
- 1.78 "Operating Costs" means, costs of goods sold, all Sales Force Costs, all Third Party Intellectual Property Costs associated with the sale of Licensed Product that are deemed Operating Costs pursuant to Section 5.6.3(c), all costs associated with the distribution, marketing and sale of Licensed Product (including costs for preparing and reproducing detailing aids, promotional materials, professional education, and product related public relations). Notwithstanding anything in this definition to the contrary, only those Operating Costs that are contemplated by the Commercialization Plan/Budget shall be chargeable by either Party as Operating Costs, with any cost overruns treated in the manner set forth in Section 5.5.4.
- 1.79 "Option Compounds" means [\* \* \*] Antibodies, [\* \* \*] Antibodies, and [\* \* \*] Antibodies.
- 1.80 "**Option Patent Rights**" means the [\* \* \*] Antibody Patent Rights, [\* \* \*] Antibody Patent Rights, and [\* \* \*] Antibody Patent Rights.
- 1.81 [Definition deleted]
- 1.82 [Definition deleted]
- 1.83 "Patent Procurement Costs" means the fees and expenses paid by the Parties or their Affiliates to outside legal counsel and experts, and Prosecuting expenses, incurred after the Effective Date, in connection with the Prosecution of Acceleron Patent Rights, Joint Patent Rights and Celgene Patent Rights, including the costs of patent interference, reexamination, reissue, opposition and revocation proceedings.
- 1.84 "Patent Rights" means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates, and patents of addition) and patent applications (including all provisional applications, continuations, continuations-in-part, and divisions), in each case, anywhere in the world.

- 1.85 "Phase 1 Clinical Trial" means, as to a specific pharmaceutical product, a Clinical Trial in humans of the safety of such product in healthy volunteers or a limited patient population, or human clinical studies directed toward understanding the mechanisms or metabolism of the product. A Phase 1 Clinical Trial shall be deemed initiated upon the dosing of the first subject or patient.
- 1.86 "Phase 2A Clinical Trial" means, as to a specific pharmaceutical product, the first Clinical Trial in humans that is intended to study the safety, dosage and initial efficacy in a limited patient population and is prospectively designed to support the continued testing of the product in one or more further Phase 2A Clinical Trials or Phase 2B Clinical Trials. A Phase 2A Clinical Trial shall be deemed initiated upon the dosing of the first patient.
- 1.87 "Phase 2B Clinical Trial" means, as to a specific pharmaceutical product, a Clinical Trial of the feasibility, safety, dose ranging and efficacy of such product, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial (or foreign equivalent) of such product, as further defined in 21 C.F.R. 312.21(b) or the corresponding regulation in jurisdictions other than the United States. A Phase 2B Clinical Trial shall be deemed initiated upon the dosing of the first patient.
- 1.88 "Phase 3 Clinical Trial" means, as to a specific pharmaceutical product, a pivotal Clinical Trial in humans performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of an NDA by a Regulatory Authority and to provide an adequate basis for physician labeling, as described in 21 C.F.R. 312.21 (c), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase 3 Clinical Trial shall be deemed initiated upon the dosing of the first patient.
- 1.89 "Post-Approval Clinical Trial" means (i) any Clinical Trial conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval and (ii) any Clinical Trial conducted after the first Regulatory Approval in the same disease state for which the Licensed Compound or Licensed Product received Regulatory Approval in the Territory.
- 1.90 "**Product Trademarks**" means the trademarks, service marks, accompanying logos, trade dress and indicia of origin used in connection with the distribution, marketing, Promotion and sale of each Licensed Product in the Territory. For purposes of clarity, the term Product Trademarks shall not include the corporate names and logos of either Party and shall include any internet domain names incorporating such Product Trademarks.
- 1.91 "**Promotion**" means those activities, including detailing normally undertaken by a Party's sales force to implement marketing plans and strategies, aimed at encouraging the appropriate use of a particular Licensed Product in a specific indication. When used as a verb, "**Promote**" means to engage in Promotion.

- 1.92 "**Prosecuting Party**" means, with respect to a particular Patent Right, the Party having primary responsibility for and control over Prosecuting such Patent Right, pursuant to <u>Section 8.2.1(a)(i)</u>.
- 1.93 "**Regulatory Approval**" means the approval necessary for the commercial manufacture, distribution, marketing, Promotion, offer for sale, use, import, export, and sale of a Licensed Product in a regulatory jurisdiction, excluding, where required, separate pricing and reimbursement approvals.
- 1.94 "**Regulatory Authority**" means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, counsel, or other government entity involved in granting of Regulatory Approval for a Licensed Product in a regulatory jurisdiction within the Territory, including the FDA and the EMEA.
- 1.95 "Royalty Term" means (a) for all countries in the Territory outside North America, the period of time beginning on the date of First Commercial Sale in a particular country and ending, on a Licensed Product-by-Licensed Product and country-by-country basis, on the later of (i) the date on which the offering for sale, selling, making, having made, using or importing such Licensed Product is no longer covered by a Valid Claim of an Acceleron Patent Right in such country and (ii) the eleventh (11th) anniversary of the First Commercial Sale of such Licensed Product in such country; and (b) for all countries in North America, to reflect Acceleron's contribution in connection with the Development Costs and co-Promotion of the Licensed Product, the period of time beginning on the date of First Commercial Sale in North America and ending, on a Licensed Product-by-Licensed Product and country-by-country basis, on the date on which the Commercialization of such Licensed Product in North America has ceased.
- 1.96 "Sales Force Costs" means all costs associated with sales representatives and training of the sales representatives, sales meetings, details, sales call reporting, work on managed care accounts, costs related to customer service and other sales and customer service related expenses. If either Party's sales force sells products other than Licensed Products, only that portion of sales force efforts that are related to the sale of Licensed Products shall be included as Sales Force Costs hereunder.
- 1.97 "Salk" means the Salk Institute for Biological Studies.
- 1.98 "Salk License" means the Exclusive License Agreement dated May 10, 2004 between Acceleron and Salk, as amended by that certain letter agreement dated February 12, 2008, a true and correct copy of which is attached hereto as Exhibit A.
- 1.99 "Sublicensee" means a sublicensee of all or part of the rights licensed to a Party under this Agreement, in compliance with the terms of Section 4.3.
- 1.100 "Territory" means all the countries of the world.
- 1.101 "Third Party" means any person or entity other than a Party or any of its Affiliates.

- 1.102 "Third Party Intellectual Property" means Patent Rights, trademarks and trademark applications and registrations, copyrights and trade secrets owned by a Third Party that would be necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field, the rights to which are obtained by a Party through a license or other means after the Effective Date.
- 1.103 "Third Party Intellectual Property Costs" means direct costs associated with the licensing or other acquisition of Third Party Intellectual Property, including upfront payments, development milestone payments, sales milestone payments, royalties, and intellectual property acquisition fees. For the avoidance of doubt, "Third Party Intellectual Property Costs" shall not include any payments owed by Acceleron to Salk or any other third party licensor pursuant to an agreement executed by Acceleron prior to the Effective Date (or, with respect to any Option Compound, prior to the date that such Option Compound is deemed a Licensed Compound in accordance with Article 7).
- 1.104 "U.S. GAAP" means generally accepted accounting principles in the United States.
- 1.105 "Valid Claim" means a claim or pending claim of a Patent Right, which claim or pending claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or other final, irrevocable action; provided, however, that if the holding of such court or agency is later reversed by a court or agency with overriding authority, the claim shall be reinstated as a Valid Claim with respect to Net Sales made after the date of such reversal; provided further, on a country-by-country basis, a patent application pending for more than five (5) years shall not be considered to have any Valid Claim for purposes of this Agreement unless and until a patent with respect to such application issues with such claim.
- 1.106 Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section
" Acceleron Indemnitees "	12.7.1
" Acceleron NA Operating Costs "	5.5.3(b)
" Acquired Party Activity "	6.3
" Audited Party "	5.7.4(b)
" Auditing Party "	5.7.4(b)
" Breaching Party "	11.2.1(a)
" Celgene Indemnitees "	12.7.2
"Commercialization Plan/Budget"	2.5
" Defending Party "	8.4.3
" Forfeited Option Compound"	6.1.1
" Indemnitee "	12.7.3
" Infringement Claim "	8.4.1
" <b>IP</b> "	11.8
" JCC Chairperson "	3.2.3
" JDC Chairperson "	3.1.3
" Joint Development Committee"	3.1.1
" Joint Commercialization Committee "	3.2.1
" Losses "	12.7.1
" Option Program Payment"	7.2
" Prosecuting " or " Prosecution "	8.2.1(a)(i)
" Publishing Party "	9.2
" Reconciliation Statement"	5.5.5
"Royalty Report"	5.6.4
" Salk Patent Rights"	8.1.1
" SPC "	8.8
"Third Party Activity"	6.2
"Third Party Intellectual Property Notice"	5.6.3(c)

### **Article 2**

### **COLLABORATION**

### 2.1 **Development**.

- 2.1.1. <u>Acceleron Responsibilities</u>. Subject to the oversight of the Joint Development Committee, Acceleron shall be solely responsible for managing all Acceleron Development Activities relating to Licensed Compounds or Licensed Products. Acceleron shall use Commercially Reasonable Efforts to carry out the Acceleron Development Activities as set forth in the applicable Development Plan/Budget to Develop Licensed Compounds and Licensed Products.
- 2.1.2. <u>Celgene Responsibilities</u>. Subject to the oversight of the Joint Development Committee, Celgene shall be solely responsible for managing all Celgene Development

Activities relating to Licensed Compounds or Licensed Products. Without limiting the foregoing, upon completion or abandonment of the initial Phase 2A Clinical Trial for a Licensed Compound or related Licensed Product, any and all further Phase 2A Clinical Trials (or early-stage Development activities) for such Licensed Compound or Licensed Product shall be performed by Celgene, unless otherwise agreed by the Joint Development Committee; provided that any Phase 2A Clinical Trials that are ongoing at the time of such completion or abandonment of such initial Phase 2A Clinical Trial shall remain the responsibility of Acceleron. Celgene shall use Commercially Reasonable Efforts to carry out the Celgene Development Activities as set forth in the applicable Development Plan/Budget to Develop Licensed Compounds and Licensed Products. Celgene shall use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for Licensed Products in the Major Market Countries.

- 2.1.3. <u>Development Plan/Budget</u>. Acceleron shall prepare the first draft of the initial Development Plan/Budget and present it to Celgene at least 15 days prior to the first meeting of the Joint Development Committee. With respect to the initial Development Plan/Budget, the Joint Development Committee shall, within sixty (60) days after the Effective Date, approve and submit to the Parties the initial Development Plan/Budget. Thereafter, the Joint Development Committee shall prepare a draft of the Development Plan/Budget at least one hundred twenty (120) days prior to the commencement of any Contract Year. During the Agreement Term, the Joint Development Committee shall, at least ninety (90) days prior to the commencement of any Contract Year during the Agreement Term, approve and submit to the Parties the Development Plan/Budget. Each Development Plan/Budget shall contain the specific Development and Manufacturing objectives to be achieved by Celgene during the Contract Year, the specific Development and Manufacturing objectives to be achieved by Acceleron during the Contract Year, and the timeline for performing such Development objectives.
- 2.1.4. <u>Payment of Development Costs</u>. The Parties shall share Development Costs and other costs associated with Development in accordance with <u>Section 5.5</u>.
- 2.1.5. <u>Consultation</u>. Celgene agrees to consult with Acceleron with respect to the Development of Licensed Products and Licensed Compounds in accordance with the provisions of <u>Section 2.9.4</u>.

### 2.2 Records.

2.2.1. <u>Generally</u>. Each Party shall, and shall require the Third Parties performing services for such Party (including Third Party contract research organizations and service providers) to, maintain scientific records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of this Agreement by such Party. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy (or request the other Party to copy) all records of the other Party maintained in connection with the work done and results achieved in the performance of this Agreement, but solely to the extent access to such records is necessary for a Party to exercise its rights under this

Agreement; <u>provided</u> that Acceleron's access to Celgene records shall be limited to records of Celgene's Development activities for the purpose of supporting Regulatory Approval in North America and Europe. All such records and the information disclosed therein shall be deemed Confidential Information pursuant to <u>Article 9</u>.

- 2.2.2. <u>Electronic Records</u>. Upon Celgene's request, Acceleron will provide Celgene reasonable assistance for Celgene to convert records provided by Acceleron to Celgene into electronic form. In addition, upon Celgene's request, Acceleron will use templates for recordkeeping provided by Celgene reasonably necessary to assist Celgene in making electronic filings with Regulatory Authorities.
- 2.2.3. <u>Security</u>. With regard to Confidential Information of the other Party, each Party shall institute reasonable security precautions and shall use reasonable efforts to (a) keep physical copies of such Confidential Information in locked locations; (b) maintain electronic copies of such Confidential Information in digitally secured locations with access permitted on a "need to know" basis; and (c) ensure that local computers are password protected and programmed to require password entry after reasonable periods of disuse.

### 2.3 Regulatory Matters.

- 2.3.1. <u>General</u>. Celgene shall develop a regulatory strategy and prepare all submissions, documents or other correspondence to be submitted to the applicable Regulatory Authorities; <u>provided</u> that the regulatory strategy and submissions to the Regulatory Authorities in North America shall be performed by Celgene in consultation with the Joint Development Committee.
- 2.3.2. North American Responsibility. Celgene shall oversee, monitor, coordinate, file, and hold in its name all North American NDAs, all communications with and submissions to North American Regulatory Authorities and all North American Regulatory Approvals with respect to Licensed Compounds and Licensed Products. All costs associated with such activities will be shared by the Parties in accordance with <a href="Article 5">Article 5</a>, including <a href="Section 5.5">Section 5.5</a>. The Parties acknowledge that IND No. [\* \* \*] has already been submitted to the FDA in Acceleron's name. Upon completion of the Phase 2A Clinical Trials or earlier if necessary for a smooth transition to Celgene of Development responsibilities or otherwise requested by Celgene, Acceleron shall assign such IND to Celgene. If any INDs are filed in Acceleron's name in connection with any Option Compound, such IND will be assigned to Celgene at such time, if any, as the Option Compound is deemed a "Licensed Compound" pursuant to Section 7.2</a>. In addition, upon Celgene's request, prior to completion of the Phase 2A Clinical Trials, Acceleron will be primarily responsible for all communications with and submissions to North American Regulatory Authorities and all North American Regulatory Approvals with respect to Licensed Compounds and Licensed Products, subject to Celgene's review and approval.
- 2.3.3. <u>North American Regulatory Meetings and Correspondence</u>. Celgene shall have primary responsibility for interfacing, corresponding and meeting with the applicable North

American Regulatory Authorities with respect to Licensed Compounds and Licensed Products. To the extent practicable, Acceleron shall be entitled to participate in all meetings and telephonic discussions between representatives of Celgene and the applicable North American Regulatory Authorities with respect to each Licensed Compound and Licensed Product. For purposes of clarification, Celgene agrees to use Commercially Reasonable Efforts to notify Acceleron of planned meetings and telephonic discussions with North American Regulatory Authorities and to use Commercially Reasonable Efforts to accommodate the schedule of Acceleron's attendees at such meetings or discussions. Celgene shall be entitled to limit, but not entirely exclude, the number of representatives of Acceleron that attend meetings and telephonic discussions with applicable North American Regulatory Authorities.

- 2.3.4. <u>Ex-North American Responsibility</u>. Celgene shall have sole responsibility to oversee, monitor, coordinate, file and hold in its name all NDAs, all other communications with and submissions to Regulatory Authorities outside of North America and all such Regulatory Approvals with respect to Licensed Compounds and Licensed Products, and shall pay all costs associated with such activities.
- 2.3.5. Review of Correspondence. To the extent practicable, Celgene shall provide Acceleron with drafts of any documents or other correspondence to be submitted (i) to the applicable Regulatory Authorities in North America, (ii) to Regulatory Authorities outside North America if for the purpose of obtaining Regulatory Approval in North America, or (iii) in connection with any Acceleron Development Activity, in each case, pertaining to each Licensed Compound or Licensed Product, sufficiently in advance of submission for Acceleron to review any such submission, and Acceleron may comment on such documents to the extent that they are intended to be submitted (i) to the applicable Regulatory Authorities in North America, (ii) to Regulatory Authorities outside North America if for the purpose of obtaining Regulatory Approval in North America, or (iii) in connection with any Acceleron Development Activity, in which case Celgene shall consider in good faith all such comments. Celgene shall provide to Acceleron, as soon as reasonably practicable, copies of any documents or other correspondence received (i) from Regulatory Authorities in North America, (ii) from Regulatory Authorities outside North America if for the purpose of obtaining Regulatory Approval in North America, or (iii) in connection with any Acceleron Development Activity, in each case, pertaining to each Licensed Compound or Licensed Product (including any meeting minutes).

#### 2.4 Manufacture and Supply.

2.4.1. <u>Phase 1 and 2 Clinical Supply</u>. Acceleron shall Manufacture all Clinical Supplies for Phase 1 Clinical Trials, Phase 2A Clinical Trials and Phase 2B Clinical Trials. The terms of supply of Clinical Supplies pursuant to this Section are set forth in <u>Exhibit B</u>, or as otherwise may be agreed to by the Parties. Notwithstanding any other provision of this Agreement, Celgene shall not be obligated to reimburse or share with Acceleron any capital expenditures costs required for Acceleron to Manufacture and supply such Clinical Supplies for Phase 1 Clinical Trials, Phase 2A Clinical Trials and Phase 2B Clinical Trials.

At Celgene's request, Acceleron shall assist Celgene in obtaining a second source for supply of Clinical Supplies in order to supply Celgene with Clinical Supplies for the Phase 2B Clinical Trials in the event Acceleron is unable to so supply in accordance with the provisions of <a href="Exhibit B">Exhibit B</a>, or as otherwise agreed to by the Parties.

- 2.4.2. Phase 3 and Post-Approval Clinical Supply. Celgene shall Manufacture and supply all Clinical Supplies for Phase 3 Clinical Trials and Post-Approval Clinical Trials; provided, however, that the Joint Development Committee may request, at least one (1) year prior to the anticipated launch of the first Phase 3 Clinical Trial or Post-Approval Clinical Trials, as applicable, that Acceleron Manufacture and supply such Clinical Supplies on terms to be agreed. Acceleron shall not unreasonably refuse such request; provided that, notwithstanding any other provision of this Agreement, Celgene shall fully reimburse Acceleron for agreed upon capital expenditures reasonably required for Acceleron to Manufacture and supply such Clinical Supplies for Phase 3 Clinical Trials or Post-Approval Clinical Trials, and otherwise the Costs of Clinical Supplies shall be allocated in accordance with Article 5, including Section 5.5. Notwithstanding any other provision of this Agreement, Acceleron shall not be obligated to reimburse or share with Celgene any capital expenditures costs required for Celgene to Manufacture and supply Clinical Supplies for Phase 3 Clinical Trials or Post-Approval Clinical Trials. For purposes of clarification, upon transition of Manufacturing and supply obligations to Celgene pursuant to this Section 2.4.2 for a particular Licensed Compound or related Licensed Product, if any Clinical Supplies are needed for additional Phase 1 Clinical Trials, Phase 2A Clinical Trials, or Phase 2B Clinical Trials for the same Licensed Compound or Licensed Product, such Manufacturing and supply responsibilities will be undertaken by Celgene in the same manner as set forth in this Section 2.4.2.
- 2.4.3. <u>Commercial Supply</u>. Celgene shall Manufacture and supply all Commercial Supplies.
- 2.4.4. <u>U.S. Manufacture</u>. To comply with United States government regulations for the licensing of federally funded inventions, Celgene, its Affiliates and any Sublicensees will commit that Licensed Products covered by the Salk Patent Rights sold in the United States will be manufactured substantially in the United States to the extent required by Applicable Law. Notwithstanding the foregoing, during the Agreement Term, upon Celgene's request, Acceleron agrees to seek a waiver from the United States government with respect to the requirement that Licensed Products for sale in the United States be manufactured substantially in the United States. Celgene understands that Acceleron cannot guarantee that such waiver can be obtained.
- 2.4.5. <u>Manufacturing Generally</u>. All Clinical Supplies and Commercial Supplies will be Manufactured in accordance with GLP and GMP, as applicable, and Applicable Law. In addition, the Manufacturing process used for Clinical Supplies and Commercial Supplies shall be in accordance with the IND, NDA, or other Regulatory Approval, as applicable, for the Licensed Product or Licensed Compound.

- 2.4.6. <u>Tech Transfer</u>. Within 30 days of Celgene's request, Acceleron shall commence the transfer to Celgene (or a Third Party selected by Celgene to Manufacture), at no cost to Celgene (unless the transfer is to a Third Party selected by Celgene), of relevant Acceleron Technology, including a chemistry, manufacturing, and controls (CMC) package and relevant manufacturing information, necessary for Celgene to Manufacture Clinical Supplies and Commercial Supplies and will use Commercially Reasonable Efforts to complete such transfer in a timely fashion. In addition, at no cost to Celgene, Acceleron shall make its personnel reasonably available for meetings or teleconferences to support and assist Celgene in the Manufacture of the Licensed Product or Licensed Compound.
- Commercialization Plan/Budget. The Joint Commercialization Committee, no later than [\* \* \*] months prior to the anticipated commercial launch of the first Licensed Product and thereafter no later than [\* \* \*] of each Contract Year, shall approve a strategic commercialization plan for the Licensed Products in the Field in North America (the "Commercialization Plan/Budget ") which sets forth the matters agreed upon by the Joint Commercialization Committee. The Joint Commercialization Committee shall prepare the initial Commercialization Plan/Budget no later than [\* \* \*] months prior to the anticipated commercial launch of the first Licensed Product. Thereafter, the Joint Commercialization Committee shall prepare a draft of the Commercialization Plan/Budget no later than [\* \* \*] of each Contract Year. The Joint Commercialization Committee will consider including (but is not required to include) (a) a multi-year marketing strategy that includes plans for market research, health economics, pricing and reimbursement, medical affairs and value added initiatives, (b) a multi-year communications strategy that includes plans for public relations, conferences and exhibitions, and other external meetings, internal meetings and communications, publications and symposia, internet activities, and core brand package, (c) a multi-year strategy for Post-Approval Clinical Trials and lifecycle management activities, (d) a high level operating plan for the implementation of such strategies on an annual basis, including information related to product positioning, core messages to be communicated, share of voice requirements and pricing strategies, (e) a commercially reasonable level of detailing activity, (f) a commercialization budget, and (g) all other activities to be conducted in connection with the Commercialization of the Licensed Products in the Field in North America. As between the Parties, Celgene will book all sales of Licensed Products and will have the sole responsibility for the sale, invoicing and distribution of the Licensed Products in the Territory.
- 2.6 **Commercialization Outside North America**. Celgene shall be solely responsible for all Commercialization activities relating to Licensed Products outside of North America. Celgene shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in each country outside North America in which Regulatory Approval for a Licensed Product is obtained.
- 2.7 **Co-Promotion of Licensed Product Within North America**. Celgene and Acceleron shall Commercialize the Licensed Products in North America in accordance with the Commercialization Plan/Budget as follows:
  - 2.7.1. <u>Commercialization Activities</u>. Within North America, the Parties will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field. In

addition, within North America, the Parties will use Commercially Reasonable Efforts to conduct the Commercialization activities assigned to them pursuant to the Commercialization Plan/Budget, including the performance of detailing in accordance therewith. In conducting the Commercialization activities, the Parties will comply with all Applicable Laws, applicable industry professional standards and compliance policies of Celgene which have been previously furnished to Acceleron, as the same may be updated from time to time and provided to Acceleron. Celgene will reasonably assist Acceleron in training sales representatives in such standards. Neither Party shall make any claims or statements with respect to the Licensed Products that are not strictly consistent with the product labeling and the sales and marketing materials approved for use pursuant to the Commercialization Plan/Budget.

- 2.7.2. <u>Sales Representatives</u>. The Commercialization Plan/Budget will set forth the number of physicians to be called on, call frequency and other matters necessary to determine the detailing effort to be utilized for Promotion in North America pursuant to the Agreement. The Commercialization Plan/Budget will allocate to each Party its portion of the total detailing effort for the aggregate of all Licensed Products across all indications in North America; <u>provided</u> that, unless otherwise agreed to by the Parties, (i) Acceleron will be allocated at least [\* \* \*] sales representatives in the United States for the Promotion of Licensed Products directed to [\* \* \*] and (ii) Acceleron will be allocated approximately [\* \* \*] of the detailing effort in each country in North America directed to [\* \* \*] and any other prescribing physicians that are not [\* \* \*]. The Joint Commercialization Committee will attempt to provide that Acceleron's assigned detailing efforts are distributed geographically within North America in a manner reasonably consistent with the distribution of the U.S. population, the Canadian population, and the Mexican population and that each Party's detailing effort will be directed to physicians of similar prescribing potential. The Sales Force Costs of Acceleron will be reimbursed pursuant to a rate set forth in the Commercialization Plan/Budget.
- 2.7.3. <u>Sales Force</u>. The Joint Commercialization Committee shall determine the number of sales representatives needed to carry out the required detailing effort. Each Party, in its sole discretion, shall create a field management structure for its sales effort. Each sales representative shall have a sales territory that allows such sales representative to perform a reasonable number of details within a reasonable geographic area ( *i.e.* , without overly-burdensome travel requirements). The effort of the Acceleron and Celgene sales forces in Promoting Licensed Products will be organized under the supervision of the Joint Commercialization Committee as to qualifications of sales representatives and field-based sales managerial personnel and the timing of hiring in light of the then-current Commercialization Plan/Budget; <u>provided</u> that the Commercialization Plan/Budget shall identify the portion of the detailing effort to be undertaken by Acceleron no later than [\* \* \*] months before the planned date of the NDA submission. At least [\* \* \*] of Acceleron's sales force planned to be available upon launch of the Licensed Product shall be hired no later than [\* \* \*] before the PDUFA date, and Acceleron's sales force shall be trained within [\* \* \*] of hiring.

- 2.7.4. <u>Training Materials and Sessions</u>. The Joint Commercialization Committee will develop Licensed Product-specific training materials and arrange for provision of such materials to each Party's sales forces. The Joint Commercialization Committee will develop a sales training program directed towards the Licensed Products. Unless otherwise mutually agreed by the Parties, Celgene and Acceleron sales representatives will participate jointly in a launch meeting for each Licensed Product, which shall include training sessions of Licensed Product-specific sales skills with respect to the approved indications for the Licensed Products. Subsequent to launch, Celgene and Acceleron shall periodically hold meetings with Acceleron and Celgene field management (down to and including district managers or their equivalents who are directly supervising territory sales representatives) to coordinate Promotion of the Licensed Products. As requested by Acceleron, Celgene shall make its management, marketing, training and other personnel reasonably available to participate in Acceleron's national and regional sales meetings and Licensed Product-training events.
- 2.7.5. <u>Promotional Materials</u>. Celgene, at its sole cost and expense, shall provide Acceleron with sales and promotional materials sufficient to permit Acceleron to perform detailing calls in a manner consistent with the detailing calls performed by the Celgene sales force. Acceleron's sales representatives will utilize only those sales and promotional materials provided to them by Celgene and will not utilize any other materials relating to or referring to the Licensed Product.
- 2.7.6. <u>Termination of Acceleron Sales Force Cost Reimbursement</u>. On a Licensed Product-by-Licensed Product and country-by-country basis in North America, on the date on which in such country there is at least one Generic Product, then Celgene shall no longer be responsible for Acceleron's Sales Force Costs under <u>Section 5.5.1 (b)</u> (or <u>Section 2.7.2</u>) with respect to such Licensed Product in such country in North America, and such Sales Force Costs will no longer be deemed Operating Costs hereunder, and Acceleron shall have no further obligation to Promote such Licensed Product or maintain a sales force for the purpose of Promoting such Licensed Product.

### 2.8 Third Parties.

2.8.1. The Parties shall be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development, Manufacturing and Commercialization activities; provided that any such utilization in North America of a Third Party (except as provided in Section 2.8.2) shall be subject to the advance notice and approval of the Joint Development Committee or Joint Commercialization Committee; provided further that Acceleron shall not be permitted to utilize Third Parties for Acceleron's Commercialization activities; provided further that each Party shall remain at all times fully liable for its respective responsibilities under each Development Plan/Budget, Commercialization Plan/Budget and this Agreement; provided further that any Third Party that Manufactures on behalf of either Party must comply with GMP and be approved or qualified by the applicable Regulatory Authority.

- 2.8.2. Notwithstanding <u>Section 2.8.1</u>, the advance notice and approval of the Joint Development Committee shall not be required in respect of the use of the Third Parties previously engaged by Acceleron under an agreement entered into prior to the Effective Date and set forth on <u>Schedule 2.8</u>; <u>provided</u> that such exception shall only apply to any services that are currently being provided under such agreements (whether pursuant to the agreements themselves or any work orders entered into in connection therewith), and Acceleron shall not be entitled to enter into new work orders or request additional services under such agreements without complying with the advance notice and approval of the Joint Development Committee.
- 2.8.3. Any agreement with a Third Party to perform a Party's responsibilities under this Agreement shall include confidentiality and non-use provisions which are no less stringent than those set forth in Article 9 of this Agreement.

### 2.9 Information Sharing.

- 2.9.1. <u>Tech Transfer</u>. In addition to the provisions of <u>Section 2.4.6</u>, within 30 days of Celgene's request, Acceleron, at no cost to Celgene, shall commence the transfer to Celgene of relevant Acceleron Technology necessary for Celgene to perform its obligations or exercise its rights hereunder and will use Commercially Reasonable Efforts to complete such transfer in a timely fashion. In addition, at no cost to Celgene, Acceleron shall make its personnel reasonably available for meetings or teleconferences to support and assist Celgene in the Development, Manufacture, and Commercialization of the Licensed Product or Licensed Compound.
- 2.9.2. Reports By Both Parties. Each Party shall keep the Joint Development Committee or the Joint Commercialization Committee fully informed about the status of the activities performed pursuant to the Development Plan/Budget, including providing the Joint Development Committee with copies of the final form of all written reports that relate to such activities, or pursuant to the Commercialization Plan/Budget, as applicable. Promptly following the Effective Date, to the extent not previously provided, Acceleron shall provide to Celgene a report describing in reasonable detail all data and information developed with respect to each Licensed Compound and Licensed Product prior to the Effective Date. From time to time during the Agreement Term, Acceleron shall provide Celgene with access to any Acceleron Technology in order to permit Celgene to perform its obligations or exercise its rights hereunder.
- 2.9.3. <u>Reports By Celgene</u>. Celgene shall keep Acceleron reasonably informed about the status of the activities performed with respect to Celgene's Development of the Licensed Product outside North America and Europe, the status of Regulatory Approvals for the Licensed Product outside North America and Europe, and the status of Celgene's Commercialization activities outside North America.
- 2.9.4. <u>Meetings</u>. [\*\*\*] on dates and times mutually agreed by the Parties, Acceleron may, at its option, send at least one Acceleron representative to meet with the Celgene product team(s) responsible for the Development and regulatory activities for each

Licensed Product and to discuss the conduct and progress of, and plans for, the Development and regulatory affairs with respect to such Licensed Product.

2.10 **ACE-536 Agreement.** Subject to the next sentence, Celgene, in its sole discretion, may decide (a) to develop and commercialize a "Licensed Compound" or "Licensed Product" under the ACE-536 Agreement (as defined below) instead of Developing and Commercializing a Licensed Compound or Licensed Product under this Agreement or (b) following the Completion of the Acceleron Phase 2 Clinical Trials (as each such term is defined in the ACE-536 Agreement), to Develop a Licensed Compound or Licensed Product hereunder instead of a "Licensed Compound" or "Licensed Product" under the ACE-536 Agreement, and, thereafter, if Celgene is undertaking "Development" or "Commercialization" (each as defined in the ACE-536 Agreement) activities in accordance with the ACE-536 Agreement with respect to a "Licensed Compound" or "Licensed Product" thereunder, Celgene will be deemed to be in compliance with any Development or Commercialization obligations under this Agreement. Celgene acknowledges that a decision to pursue the scenario described in subsection (b) will not be made based primarily on Celgene's payment obligations to Acceleron under this Agreement or the ACE-536 Agreement, but rather will take into consideration such things as the resources as would normally be exerted or employed by a similarly-situated biopharmacecutical company, product life, stage of development, safety and efficacy, development costs, operating costs, the anticipated prescription label, the nature of the product, the clinical setting in which the product is expected to be used, competitiveness of the marketplace, regulatory environment, the patent or other proprietary position of the product, and other clinical, commercial, regulatory or manufacturing conditions then prevailing.

### Article 3

#### COLLABORATION MANAGEMENT

### 3.1 **Joint Development Committee** .

- 3.1.1. <u>Establishment</u>. Within 45 days after the Effective Date, the Parties shall establish, and have the first meeting of, a joint development committee to facilitate Development of Licensed Compounds and Licensed Products during the Agreement Term (the "**Joint Development Committee**"). In advance of the formation of the Joint Development Committee, either Party may request that the Parties, and the other Party agrees that they shall, meet (in person or by teleconference) for the purposes of facilitating the performance by each Party of its activities hereunder.
- 3.1.2. <u>Membership</u>. Unless otherwise agreed by the Parties, the Joint Development Committee shall be comprised of three (3) representatives from each Party with one (1) representative with relevant decision-making authority from each Party such that the Joint Development Committee is able to effectuate all of its decisions within the scope of its responsibilities as set forth in <u>Section 3.1.5</u> below. Either Party may replace or substitute its respective representatives to the Joint Development Committee at any time with prior notice to the other Party, <u>provided</u> that such replacement or substitute is of comparable authority within that Party. Upon mutual agreement of the Parties, additional

representatives or consultants may be invited to attend a Joint Development Committee meeting, subject to such representatives' and consultants' written agreement to comply with the requirements of <u>Article 9</u>. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives.

- 3.1.3. <u>Chairperson</u>. The Chairperson of the Joint Development Committee (the "**JDC Chairperson**") shall be Celgene's representative. The JDC Chairperson's responsibilities shall include (a) scheduling meetings; (b) setting agendas for meetings with solicited input from Acceleron's representatives; (c) preparing and confirming minutes of the meetings, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations made by the Joint Development Committee and delivering minutes to each Party's senior management for review and final approval; and (d) conducting meetings.
- 3.1.4. <u>Meetings</u>. The Joint Development Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, at least once per [\* \* \*] (and more frequently as the Joint Development Committee determines is necessary to fulfill its responsibilities), with the location for such meetings alternating between Acceleron's facilities and Celgene's facilities (or such other locations as are determined by the Joint Development Committee). Alternatively, if the Parties agree, the Joint Development Committee may meet by means of teleconference, videoconference or other similar communications equipment. In connection with any transition of responsibilities from Acceleron to Celgene (including the transition of Manufacturing responsibility), the Joint Development Committee shall meet and discuss how best to transition such responsibilities to Celgene and, in connection with Manufacturing responsibility, shall establish a supply transition plan with respect to the applicable Licensed Product. Acceleron shall cooperate fully to assist in transitioning to Celgene all applicable responsibilities.
- 3.1.5. <u>Responsibilities</u>. The Joint Development Committee shall have the following responsibilities:
  - (a) reviewing and approving (i) the initial Development Plan/Budget and each annual Development Plan/Budget and (ii) any proposed modifications to such Development Plan/Budget, in each case in accordance with the time frames set forth in Section 2.1.3;
  - (b) developing a publication strategy for Development activities and results arising out of this Agreement;
  - (c) facilitating the transfer of Know-How and Confidential Information between the Parties for purposes of conducting the Development Plan/Budget;
  - (d) reviewing the progress of the Parties in their conduct of the Development Plan/Budget against the timelines and budgets contained therein, reviewing relevant data and considering issues of priority;

- (e) approving the licensing of Third Party technology, as described in Section 5.6.3(c);
- (f) performing such other activities as are contemplated under this Agreement and that the Parties mutually agree shall be the responsibility of the Joint Development Committee; and
- (g) defining a target Licensed Product profile after consultation with the Parties' respective commercial managers.

#### 3.2 **Joint Commercialization Committee**.

- 3.2.1. <u>Establishment</u>. Promptly after the Effective Date, the Parties shall establish a joint commercialization committee to facilitate Commercialization of Licensed Compounds and Licensed Products in North America during the Agreement Term (the "**Joint Commercialization Committee**").
- 3.2.2. Membership. Unless otherwise agreed by the Parties, the Joint Commercialization Committee shall be comprised of three (3) representatives from each Party with one (1) representative with relevant decision-making authority from each Party such that the Joint Commercialization Committee is able to effectuate all of its decisions within the scope of its responsibilities as set forth in Section 3.2.5 below. Either Party may replace or substitute its respective representatives to the Joint Commercialization Committee at any time with prior notice to the other Party, provided that such replacement or substitute is of comparable authority within that Party. Upon mutual agreement of the Parties, additional representatives or consultants may be invited to attend a Joint Commercialization Committee meeting, subject to such representatives' and consultants' written agreement to comply with the requirements of Article 9. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives. In the event that that Acceleron ceases to continue to appoint members of the Joint Commercialization Committee, Celgene shall deliver all notices of activities of the Joint Commercialization Committee and materials relating to Commercialization of Licensed Products to the Vice President of Sales & Marketing of Acceleron; and, notwithstanding Acceleron's lack of membership on the Joint Commercialization Committee, Acceleron shall remain obligated to perform its obligations hereunder with respect to the Commercialization Committee, as provided herein.
- 3.2.3. <u>Chairperson</u>. The Chairperson of the Joint Commercialization Committee (the "**JCC Chairperson**") shall be Celgene's representative. The JCC Chairperson's responsibilities shall include (a) scheduling meetings; (b) setting agendas for meetings with solicited input from Acceleron's representatives; (c) preparing and confirming minutes of the meetings, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations made by the Joint Commercialization Committee and delivering minutes to each Party's senior management for review and final approval; and (d) conducting meetings.

- 3.2.4. <u>Meetings</u>. The Joint Commercialization Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, at least once per [\* \* \*] (and more frequently as the Joint Commercialization Committee determines is necessary to fulfill its responsibilities), with the location for such meetings alternating between Acceleron's facilities and Celgene's facilities (or such other locations as are determined by the Joint Commercialization Committee); <u>provided</u> that, unless otherwise agreed to by the Parties, the Joint Commercialization Committee shall not be required to meet earlier than the time necessary to complete the activities contemplated by <u>Section 2.5</u>. Alternatively, if the Parties agree, the Joint Commercialization Committee may meet by means of teleconference, videoconference or other similar communications equipment.
- 3.2.5. Responsibilities. The Joint Commercialization Committee shall have the following responsibilities:
  - (a) establishing the strategy for the Commercialization of Licensed Products in the Field in North America;
  - (b) developing and approving the Commercialization Plan/Budget in accordance with <u>Section 2.5</u>, as well as updating the Commercialization Plan/Budget and amending the Commercialization Plan/Budget from time to time as appropriate;
  - (c) subject to the specific terms and conditions hereof, allocating responsibilities under the Commercialization Plan/Budget to the Parties in accordance with the Parties' abilities to perform such activities in the most efficient and cost effective manner;
  - (d) overseeing the implementation of the strategy for Commercializing the Licensed Products in the Field in North America (including strategies related to regulatory approvals, reimbursement, advertising and promotion, brand integrity, sales, and launch sequence as set forth in the Commercialization Plan/Budget);
  - (e) providing input to the Joint Development Committee regarding the target product profile for the Licensed Products and making recommendations regarding changes to the same;
  - (f) approving the licensing of Third Party technology, as described in <u>Section 5.6.3(c)</u>;
  - (g) reviewing the Parties' marketing and promotional activities in North America to ensure that such activities are consistent with the Commercialization Plan/Budget; and
  - (h) performing such other activities as are contemplated under this Agreement and that the Parties mutually agree shall be the responsibility of the Joint Commercialization Committee.

- 3.3 **Joint Responsibilities of the Joint Development Committee and Joint Commercialization Committee**. In addition to the independent Joint Development Committee and Joint Commercialization Committee meetings, the Joint Development Committee and the Joint Commercialization Committee shall coordinate to hold joint meetings as appropriate to discuss issues which are relevant to both Development and Commercialization, including in order to: (i) establish the target product profile for the Licensed Products (including indications for which the Licensed Products will be Developed and Commercialized, key labeling claims required for commercial success of the Licensed Products given the competitive environment, and any other key product features and benefits which will be used to Develop or support a promotional message or reimbursement status for the Licensed Products), (ii) discuss development of the Licensed Product for additional indications and alternative delivery forms, (iii) discuss development of improvements in formulation, presentation and other features of Licensed Products considered desirable for life cycle management and maximizing sales of the Licensed Products throughout North America, and (iv) set the end point criteria to determine whether a Clinical Trial or other Development activity is deemed successful. Such joint meetings may be held by videoconference, teleconference or in person and any decisions required to be taken shall be submitted to the Joint Development Committee or Joint Commercialization Committee for resolution in accordance with the terms hereof.
- 3.4 **Appointment of Subcommittees and Project Teams**. The Joint Development Committee and Joint Commercialization Committee may each create such subcommittees or project teams as such committee deems necessary to carry out its responsibilities. Each such subcommittee and project team shall report recommendations and proposed actions to the Joint Development Committee or Joint Commercialization Committee, as applicable, which shall approve or reject such recommendations or actions proposed in accordance with the terms of this Agreement.
- 3.5 **Decision-Making**. The Joint Development Committee and Joint Commercialization Committee shall each act by unanimous agreement of its members, with each Party having one vote. If the Joint Development Committee or Joint Commercialization Committee, after [\* \* \*] (or such other period as the Parties may otherwise agree) of good faith efforts to reach a unanimous decision on an issue, fails to reach such a unanimous decision, then either Party may refer such issue to the Executive Officers. Such Executive Officers shall meet promptly thereafter and shall negotiate in good faith to resolve the issues. If Executive Officers cannot resolve such issue within [\* \* \*] of referral of such issue to the Executive Officers, the resolution of such issue shall be determined by Celgene. Notwithstanding the foregoing, none of Celgene, the Joint Development Committee and the Joint Commercialization Committee may make any decision inconsistent with the express terms of this Agreement without the prior written consent of each Party.
- 3.6 **Dispute Resolution**. With respect to any disputes between the Parties concerning this Agreement that are not subject to the oversight of the Joint Development Committee or the Joint Commercialization Committee, either Party may submit the dispute to senior management of Celgene and Acceleron for review. If the dispute cannot be resolved within [\* \* \*] despite such escalation, then either Party may refer the matter to the Executive Officers to be resolved by

negotiation in good faith as soon as is practicable but in no event later than [\* \* \*] after referral. Such resolution, if any, by the Executive Officers shall be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such [\* \* \*] period, then such matter shall be resolved in accordance with Section 13.1 hereof.

- 3.7 **Dissolution**. The Joint Development Committee and Joint Commercialization Committee shall each be dissolved upon expiration of the Agreement Term, or earlier upon mutual written agreement of the Parties.
- 3.8 **Appointment of Joint Development Committee and Joint Commercialization Committee Members**. Notwithstanding the above, at all times after [\* \* \*] years from the Effective Date, Acceleron's membership and participation on the Joint Development Committee, the Joint Commercialization Committee, and any related subcommittees shall be at Acceleron's sole option. If, after [\* \* \*] years from the Effective Date, Acceleron does not appoint members of the Joint Development Committee or the Joint Commercialization Committee, it shall not be a breach of this Agreement, and, thereafter, Celgene shall, in its own sole discretion, make all decisions for, and take all actions for, the Joint Development Committee or Joint Commercialization Committee, as applicable, pursuant to the terms and conditions of this Agreement, and Acceleron shall comply with all such decisions of Celgene.

#### Article 4

#### LICENSES AND INTELLECTUAL PROPERTY OWNERSHIP

- 4.1 **License Grants to Celgene** . Subject to the terms and conditions of this Agreement, Acceleron hereby grants to Celgene and its Affiliates during the Agreement Term an exclusive, royalty-bearing license (which shall, however, be co-exclusive with Acceleron solely to permit Acceleron to perform the Acceleron Development Activities, Manufacturing responsibilities, and co-Promotion activities to the extent provided herein) under the Acceleron Technology and Acceleron's interest in the Joint Technology to offer for sale, sell, make, have made, use and import Licensed Compounds and Licensed Products in the Field in the Territory. For avoidance of doubt, such license includes the right to Develop, Manufacture and Commercialize Licensed Compounds and Licensed Products in the Field in the Territory.
- 4.2 **License Grant to Acceleron**. Subject to the terms and conditions of this Agreement, Celgene hereby grants Acceleron during the Agreement Term a non-exclusive royalty-free license under the Celgene Technology solely to perform its Development and co-Promotion obligations pursuant to the Development Plan/Budget and Commercialization Plan/Budget, as applicable, and to Manufacture Licensed Compounds and Licensed Products in accordance with this Agreement.

#### 4.3 Sublicenses.

4.3.1. <u>Celgene's Right to Sublicense</u>. Celgene may sublicense the rights granted to it under <u>Section 4.1</u>, in whole or in part, through one or more tiers to one or more of its Affiliates or Third Parties at any time; <u>provided</u>, <u>however</u>, that the sublicense, to the extent

it involves the sublicense of any Salk Patent Rights, will be subject to the terms and conditions of Section 2.2 of the Salk License. In the event that Celgene enters into any sublicense (other than a sublicense to an Affiliate) that includes North America as a territory, in whole or in part, then, such sublicense shall not modify Acceleron's right to participate in Collaboration matters as provided in <a href="Article 2">Article 2</a> (Collaboration) and <a href="Article 3">Article 3</a> (Collaboration Management) or under the cost sharing provisions of <a href="Section 5.5">Section 5.5</a>. Celgene shall remain responsible for the performance of its Sublicensees under this Agreement, including for all payments due hereunder, whether or not such payments are made by Celgene, its Affiliates or its Sublicensees. Celgene shall provide Acceleron with notice and a copy of each sublicense, and any modification or termination thereof, promptly (and in any event within [\* \* \*] days after such agreement has been fully executed) after execution of such sublicense, modification or termination; <a href="provided">provided</a> that any such copy may be redacted to remove any confidential, proprietary or competitive information of Celgene or its Sublicensee, but such copy shall not be redacted to the extent that it impairs Acceleron's or Salk's ability to ensure compliance with this Agreement or the Salk License, as applicable. All such notices and copies of sublicenses provided by Celgene under this <a href="Section 4.3.1">Section 4.3.1</a> shall be deemed to be Confidential Information of Celgene subject to the provisions of <a href="Article 9">Article 9</a> hereof whether or not so marked.

- 4.3.2. <u>Terms</u>. Each sublicense granted by Celgene pursuant to <u>Section 4.3.1</u> shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement. Agreements with any Commercializing Sublicensee shall contain the following provisions: (a) a requirement that such Sublicensee submit applicable sales or other reports consistent with those required hereunder; (b) an audit requirement similar to the requirement set forth in <u>Section 5.7.4</u>; and (c) a requirement that such Sublicensee comply with the confidentiality and non-use provisions of <u>Article 9</u> with respect to both Parties' Confidential Information.
- 4.3.3. <u>Effect of Termination</u>. Except as otherwise provided in the sublicense agreement, if this Agreement terminates for any reason, any Celgene Sublicensee shall, from the effective date of such termination, automatically become a direct licensee of Acceleron with respect to the rights originally sublicensed to the Sublicensee by Celgene; <u>provided</u>, <u>however</u>, that such Sublicensee is not in breach of its sublicensee agreement and continues to perform thereunder. Notwithstanding the foregoing, Acceleron shall not be liable to such Sublicensee with respect to any obligations of Celgene to the Sublicensee.

### 4.4 Ownership of and Rights to Intellectual Property.

4.4.1. Ownership of Improvements/Collaboration IP. Each Party agrees promptly to disclose to the other Party all Improvements and all Collaboration IP made by or under authority of such Party under this Agreement. As between the Parties, (a) title to all Celgene Improvements and Celgene Collaboration IP shall be owned by Celgene, (b) title to all Acceleron Improvements and Acceleron Collaboration IP shall be owned by Acceleron, and (c) title to all Joint Improvements and Joint Collaboration IP shall be jointly owned by Celgene and Acceleron. Acceleron hereby assigns, and Acceleron shall cause its

employees, consultants, and agents to assign, its right, title, and interest in and to all Celgene Improvements to Celgene.

- 4.4.2. <u>Joint Improvements/Collaboration IP</u>. Subject to the rights herein, each Party shall have the right to practice and exploit Joint Improvements and Joint Collaboration IP, without any obligation to account to the other for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit Joint Improvements and Joint Collaboration IP, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such approval or accounting; and to the extent there are any Applicable Laws that prohibit such a waiver, each Party will be deemed to so consent. Each Party agrees to be named as a party, if necessary, to bring or maintain a lawsuit involving a Joint Improvement or Joint Collaboration IP.
- 4.4.3. <u>Data</u>. All data generated in the course of Clinical Trials hereunder shall be owned by Celgene and deemed "Celgene Know-How." Acceleron hereby assigns, and Acceleron shall cause its employees, consultants, and agents to assign, its right, title, and interest in and to such data and information to Celgene.
- 4.4.4. <u>Celgene IP</u>. Celgene is and shall remain the sole owner of the Celgene Technology.
- 4.4.5. <u>Acceleron IP</u>. Acceleron is and shall remain the sole owner of the Acceleron Technology.
- 4.4.6. <u>Disputes as to Inventorship and Ownership of Improvements and Collaboration IP</u>. Should the Parties fail to agree regarding inventorship of any invention made in the conduct of activities under this Agreement or the ownership of Improvements and Collaboration IP arising out of this Agreement, the Parties shall refer the matter to a mutually agreed-upon outside counsel for resolution. All determinations of inventive contribution for inventions arising hereunder shall be determined under United States patent law. The Parties agree that each of the individuals listed on <u>Schedule 4.4.6</u> are acceptable outside counsel for such resolution, and neither Party will use such individuals (or the law firms for whom such individuals work) for any legal services without the prior written consent of the other Party. The costs of such outside counsel shall be borne equally by the Parties.

### 4.5 Salk License.

4.5.1. <u>Acknowledgement</u>. Except as provided in <u>Section 4.5.2</u>, Acceleron acknowledges that it is responsible for the fulfillment of its obligations under the Salk License and agrees to fulfill the same, including any provisions necessary to maintain in effect any rights sublicensed to Celgene hereunder and the exclusive nature of such rights, subject to Celgene's compliance with its obligations hereunder. In the event of any conflict between the terms of this Agreement and the Salk License, the Parties will discuss in good faith how to address the conflict; <u>provided</u> that, if the Parties are unable to agree on how to address the conflict, the terms of this Agreement shall govern. Notwithstanding the foregoing,

Celgene acknowledges that (i) the Salk License limits Acceleron from sublicensing under the Salk Patent Rights of any right with regard to Secondary Licensed Products (as defined in the Salk License), other than a sublicense of a Primary Licensed Product (including a Primary Licensed Product that subsequently becomes a Secondary Licensed Product) or in connection with a sublicense of a Secondary Licensed Product that is first discovered or identified by Acceleron, and (ii) the licenses under the Salk License are limited to therapeutic products, and diagnostic products are only permitted with respect to Secondary Licensed Products. Celgene further acknowledges that the Salk License provides for the right of Salk to (a) Prosecute the Salk Patent Rights and (b) make and use, and to permit others at academic, government and non-profit institutions to make and use, the Salk Patent Rights. Celgene additionally acknowledges that the Salk Patent Rights supported by federal funding are subject to certain obligations to the United States government as provided in the Salk License.

- 4.5.2. <u>Incorporation of Certain Provisions</u>. Celgene acknowledges and agrees that it shall be bound by the following provisions of the Salk License, as if Celgene was a "Licensee" thereunder: [\* \* \*]; <u>provided</u> that, with respect to <u>Section</u> [\* \* \*], the Parties acknowledge that, as provided in <u>Exhibit A</u> to the Salk License, no "Biological Materials" have been provided to Acceleron, and Acceleron will not request or accept any "Biological Materials" from Salk without Celgene's prior written consent (which consent may be conditioned on, among other things, confirmation that the "Biological Materials" license under the Salk License is sublicensable to Celgene); <u>provided further</u> that, notwithstanding Celgene's agreement to be bound by Section [\* \* \*] of the Salk License, as between Acceleron and Celgene, the obligation to indemnify Salk pursuant to such section will be allocated between Acceleron and Celgene in accordance with <u>Section 12.7</u> hereof. The Parties acknowledge that no [\* \* \*] has been provided to Celgene, except [\* \* \*].
- 4.5.3. <u>Covenants Regarding the Salk License</u>. Acceleron agrees that during the Agreement Term:
  - (a) Acceleron shall not modify or amend the Salk License in any way that could adversely affect Celgene's rights or economic interest under this Agreement without Celgene's prior written consent;
  - (b) Acceleron shall not terminate the Salk License in whole or in part, without Celgene's prior written consent, if such termination would affect Celgene's license granted hereunder;
  - (c) Acceleron shall be solely responsible for, and shall make, all royalty, milestone, and other payments owed to Salk pursuant to the Salk License:
  - (d) Acceleron shall not exercise or fail to exercise any of Acceleron's rights or obligations under the Salk License that relate to the Licensed Compounds, Licensed Products, or Celgene's rights hereunder (including the right to negotiate with Salk with respect to "Inventions" under Section 2.4 of the Salk License), in each case, without the prior written consent of Celgene, not to be unreasonably

withheld; and, at the reasonable request of Celgene, Acceleron shall exercise such rights and make such requests as are permitted under the Salk License;

- (e) Acceleron shall promptly furnish Celgene with copies of all reports and other communications that Acceleron furnishes to Salk that relate to the subject of this Agreement;
- (f) Acceleron shall promptly furnish Celgene with copies of all reports and other communications that Acceleron receives from Salk that relate to the subject of this Agreement;
- (g) Acceleron shall furnish Celgene with copies of all notices received by Acceleron relating to any alleged breach or default by Acceleron under the Salk License within [\* \* \*] after Acceleron's receipt thereof; in addition, if Acceleron should at any time breach the Salk License or become unable to timely perform its obligations thereunder, Acceleron shall immediately notify Celgene;
- (h) If Acceleron cannot or chooses not to cure or otherwise resolve any alleged breach or default under the Salk License, Acceleron shall so notify Celgene within [\* \* \*] of such decision, which shall not be less than [\* \* \*] prior to the expiration of the cure period under the Salk License; <u>provided</u> that Acceleron shall use Commercially Reasonable Efforts to cure any such breach or default; and
- (i) Celgene, in its sole discretion, shall be permitted [\* \* \*] in accordance with the terms and conditions of the Salk License or otherwise [\* \* \*]; and, if Celgene [\* \* \*].
- 4.5.4. <u>Survival of Celgene's Rights</u>. As provided in Section 2.2 and 10.3(a)(iv) of the Salk License, in the event of termination of the Salk License, Celgene's rights hereunder will survive in accordance with the terms of such sections. The Parties agree that [\* \* \*], without Celgene's prior written consent, shall be deemed a material breach of this Agreement by Acceleron; <u>provided</u> that (a) if [\* \* \*], Celgene agrees to use Commercially Reasonable Efforts to assist Acceleron in [\* \* \*], and (b) if [\* \* \*] shall not be deemed a material breach by Acceleron of this Agreement.
- 4.6 **No Other Rights** . Except as otherwise provided in this Agreement, neither Party shall obtain any ownership interest or other right in any Know-How or Patent Rights owned or Controlled by the other Party.

#### **Article 5**

### FINANCIAL PROVISIONS

5.1 **Upfront Payments** . Celgene shall make the following payments to Acceleron within ten (10) days of the Effective Date: (i) thirty-five million dollars (\$35,000,000) as an upfront, non-

creditable, non-refundable fee, relating to the license grants set forth in <u>Article 4</u>, and (ii) ten million dollars (\$10,000,000) as an upfront, non-creditable, non-refundable fee, relating to the option program set forth in <u>Article 7</u>.

5.2 **ActRIIA Development Milestones**. For any Licensed Compound or Licensed Product containing ActRIIA, Celgene shall pay to Acceleron the amounts set forth below no later than [\* \* \*] days after the earliest date on which the corresponding milestone event has first been achieved with respect to a Licensed Compound or Licensed Product in each indication described below:

Milestone Event	Payment for Each Indication		
	Oncology	Non-Oncology	
Dosing the first patient in the first Phase 2B Clinical Trial for the purposes of obtaining Regulatory Approval in the United States	N/A	\$7,000,000	
Dosing the first patient in the first Phase 3 Clinical Trial for the purposes of obtaining Regulatory Approval in the United States	\$10,000,000	\$10,000,000	
[* * *]	\$[* * *]	\$[* * *]	
[* * *]	\$[* * *]	\$[* * *]	
[* * *]	\$[* * *]	\$[***]	
[***]	\$[***]	\$[* * *]	
[***]	\$[***]	\$[* * *]	
[***]	\$[* * *]	\$[* * *]	

A Clinical Trial or NDA will fall within the oncology indication if the Licensed Compound or Licensed Product is used (a) to treat a patient for cancer or (b) to treat a patient for a disease, disorder, or condition that results from the patient having, or being treated for, cancer. All other Clinical Trials or NDAs will fall within the non-oncology indication. For example, use of a Licensed Compound or Licensed Product to treat [\* \* \*] will be deemed to fall within the oncology indication, and, for purposes of this Agreement, the treatment of anemia in a patient with [\* \* \*] will be considered oncology and will be deemed to fall within the oncology indication; on the other hand, [\* \* \*] not caused by any oncologic condition or treatment thereof will fall within the non-oncology indication (whether or not the patients taking the Licensed Compound or Licensed Product has cancer or a disease, disorder, or condition that results from the patient having, or being treated for, cancer). For the avoidance of doubt, a single Clinical Trial or NDA shall not trigger an obligation by Celgene to pay milestones with respect to both the oncology and non-oncology indications but instead shall be treated as falling only within one indication or the other and requiring not more than one milestone payment; provided that, if the Parties initially elect one indication (e.g., oncology) to apply to a Licensed Compound or Licensed Product but later determine it is not effective for that indication, the Parties may then

elect to proceed with the other indication (*e.g.*, non-oncology) for such Licensed Compound or Licensed Product; however, notwithstanding the last sentence of the next paragraph, such Licensed Compound or Licensed Product shall only trigger milestones in the new indication (in this example, non-oncology) that occur after such election and shall not trigger any earlier milestones in the new indication.

For clarity, the milestone payments set forth in this Section 5.2 shall be paid only once for each indication, regardless of how many Licensed Compounds and Licensed Products may achieve the milestone event and regardless of whether the same Licensed Compound or Licensed Product achieves the milestone event for the same indication more than once. By way of a nonlimiting example, if a Licensed Compound and a Licensed Product achieve the same milestone event in the same indication, only one payment is due. Furthermore, to the extent a Licensed Compound or Licensed Product fails and a replacement Licensed Compound or Licensed Product is selected, any milestones previously paid for such failed Licensed Compound or Licensed Product shall not be paid a second time with respect to such replacement Licensed Compound or Licensed Product. Except as provided in the prior paragraph, to the extent that any prior milestone has not been paid at the time of achievement of a subsequent milestone, then upon the achievement of such subsequent milestone all preceding unpaid milestone payments shall be made in addition to the payment corresponding to the milestone that has been achieved; provided that the acceptance or approval of [\* \* \*] shall not be deemed to trigger any milestone payment for [\* \* \*] in any other country or jurisdiction.

For purposes of determining the occurrence of milestones under this <u>Section 5.2</u> and <u>Section 5.3</u>, [\* \* \*] shall be deemed to have occurred [\* \* \*] days following [\* \* \*]; <u>provided</u> that, if such [\* \* \*], such [\* \* \*] shall not be deemed to have occurred until such comments have been addressed to the satisfaction of [\* \* \*].

The Parties agree that, effective as of the execution of the First Amendment to this Agreement, Celgene shall have no obligations to pay any amounts due pursuant to the provisions of Section 5.2 (including the table of milestones set forth therein) prior to such amendment, and the provisions of this Section 5.2 (including the table of milestones set forth herein) will replace such former provisions in their entirety. Acceleron acknowledges and agrees that all payments that were due pursuant to the provisions of the former Section 5.2 were paid in full.

5.3 **Option Compound Development Milestones**. Provided that the option in <u>Article 7</u> is exercised in full, for a Licensed Compound or Licensed Product containing an [\* \* \*] Antibody, [\* \* \*] Antibody, or [\* \* \*] Antibody, Celgene shall also pay to Acceleron the amounts set forth below no later than [\* \* \*] days after the earliest date on which the corresponding milestone event has first been achieved with respect to any such Licensed Compound or Licensed Product (for the avoidance of doubt, the milestones set forth below shall be payable separately with respect to a Licensed Compound or Licensed Product containing an [\* \* \*] Antibody, an [\* \* \*] Antibody or a [\* \* \*] Antibody):

<u>Milestone Event</u>	Payment for Each Indication for [ * * * ] Antibodies, [ * * * ]  Antibodies and [ * * * ] Antibodies	
	Oncology	Non-Oncology
[* * *]	\$[* * *]	\$[***]
[* * *]	\$[* * *]	\$[***]
[* * *]	\$[* * *]	\$[***]
[* * *]	\$[* * *]	\$[* * *]
[* * *]	\$[* * *]	\$[***]
[* * *]	\$[***]	\$[***]
[* * *]	\$[***]	\$[***]
[***]	\$[* * *]	\$[* * *]

The determination of whether a Clinical Trial or NDA falls within the oncology indication or non-oncology indication will be made in the same manner as provided in <u>Section 5.2</u>.

For clarity, the milestone payments set forth in this Section 5.3 shall be paid only once for each indication for a Licensed Compound or Licensed Product the underlying Licensed Compound of which is an [\* \* \*] Antibody, once for each indication for a Licensed Compound or Licensed Product the underlying Licensed Compound of which is an [\* \* \*] Antibody, and once for each indication for a Licensed Compound or Licensed Product the underlying Licensed Compound of which is a [\* \* \*] Antibody, regardless of how many Licensed Compounds and Licensed Products with such Licensed Compound may achieve the milestone event and regardless of whether the same Licensed Compound or Licensed Product achieves the milestone event for the same indication more than once. By way of a nonlimiting example, if an [\* \* \*] Antibody Licensed Compound and a Licensed Product containing an [\* \* \*] Antibody achieve the same milestone event in the same indication, only one payment is due; if an [\* \* \*] Antibody Licensed Compound and a Licensed Product containing an [\* \* \*] Antibody achieve the same milestone event in the same indication, only one payment is due; and if a [\* \* \*] Antibody Licensed Compound and a Licensed Product containing a [\* \* \*] Antibody achieve the same milestone event in the same indication, only one payment is due. In addition for clarity, if an [\* \* \*] Antibody Licensed Compound or Licensed Product achieves a particular milestone, and an [\* \* \*] Antibody Licensed Compound or Licensed Product achieves the same milestone, the particular milestone payment will be made twice, once with respect to the [\* \* \*] Antibody Licensed Compound or Licensed Product and once with respect to the [\* \* \*] Antibody Licensed Compound or Licensed Product. Furthermore, to the extent a Licensed Compound or Licensed Product the underlying Licensed Compound of which is an [\* \* \*] Antibody, [\*\*\*] Antibody, or [\*\*\*] Antibody fails and a replacement Licensed Compound or Licensed Product with the same Licensed Compound is selected, any milestones previously paid for such failed Licensed Compound or Licensed Product shall not be paid a second time with respect to such replacement Licensed Compound or Licensed Product. To the extent that any prior milestone has not been paid at the time of achievement of a subsequent milestone, then upon the achievement of such subsequent milestone all preceding unpaid milestone payments shall be made in addition to the payment corresponding to the milestone that has been achieved; provided that the acceptance or

approval of an NDA in any one country or jurisdiction shall not be deemed to trigger any milestone payment for the acceptance or approval of an NDA in any other country or jurisdiction.

The Parties agree that, effective as of the execution of the First Amendment to this Agreement, Celgene shall have no obligations to pay any amounts due pursuant to the provisions of Section 5.3 (including the table of milestones set forth therein) prior to such amendment, and the provisions of this Section 5.3 (including the table of milestones set forth herein) will replace such former provisions in their entirety. Acceleron acknowledges and agrees that all payments that were due pursuant to the provisions of the former Section 5.3 were paid in full.

5.4 **Ex-North American Sales Milestones**. Celgene shall also pay to Acceleron the amounts set forth below no later than [\* \* \*] days after the earliest date on which the corresponding milestone event has first been achieved with respect to each Licensed Product:

<u>Milestone Event</u>	<u>Payment</u>
[***]	\$[* * *]
[***]	\$[* * *]
[***]	\$[* * *]

Once Celgene has made any particular milestone payment under this <u>Section 5.4</u>, Celgene shall not be obligated to make any payment under this <u>Section 5.4</u> with respect to the re-occurrence of the same milestone for the same Licensed Product (regardless of how many indications the Licensed Product may be approved for). For making the determinations under this <u>Section 5.4</u>, Net Sales shall be derived from audited financial statements of Celgene (or the applicable Affiliate or Sublicensee); <u>provided</u>, <u>however</u>, that Celgene shall use U.S. GAAP to calculate in good faith the Net Sales derived from any entities that are not audited or have not completed their audit within [\* \* \*] days after the end of the preceding Contract Year. For clarity, two dosage forms of a product would constitute the same Licensed Product; however, any derivatives and modifications of a Licensed Product are considered distinct Licensed Products, other than modifications that are limited to changes in the formulation of a Licensed Product (which formulation modifications would constitute the same Licensed Product).

#### 5.5 **Sharing Costs**.

- 5.5.1. Cost Sharing. The Parties shall be responsible for paying costs as set forth in this Section.
  - (a) Subject to Section 5.5.1(b)(ii) and (iii), for all North American and European Development Costs incurred prior to January 1, 2013, Acceleron shall be responsible for paying [\* \* \*] percent [\* \* \*] and Celgene shall be responsible

for paying [\* \* \*] percent [\* \* \*] of such North American and European Development Costs.

- (b) Celgene shall be responsible for paying one hundred percent (100%) of (i) all Development Costs (other than North American and European Development Costs), (ii) all North American and European Development Costs incurred on or after January 1, 2013, (iii) all [\* \* \*] that comprise part of North American And European Development Costs and are incurred after the Effective Date of the First Amendment to this Agreement, and (iv) [\* \* \*]; provided that the Parties acknowledge and agree that Acceleron will not be incurring any such costs described in clause (i) or (iv) (other than [\* \* \*] or other [\* \* \*] that are specifically set forth in the [\* \* \*]).
- (c) Patent Procurement Costs shall be shared in accordance with the provisions of <u>Section 8.2.4</u>.
- (d) Except for approved costs incurred by Acceleron pursuant to <u>Section 2.4.2</u>, purchases of capital equipment related to Manufacturing (*e.g.*, the purchase and qualification of a manufacturing facility or of additional manufacturing lines) shall not be included in any cost to be shared under this Agreement.
- 5.5.2. <u>Sharing Mechanics</u>. The payment of costs pursuant to this Agreement shall be subject to the following:
  - (a) Notwithstanding anything in this Agreement to the contrary, no cost, expense, amount or sum allocable or chargeable to the Parties' activities under this Agreement shall be allocated or charged more than once. Unless otherwise specifically authorized by the Parties or this Agreement, all costs, expenses, amounts or sums to be charged or allocated by one Party to the other Party under this Agreement shall not be so chargeable or allocable unless they are directly related to this Agreement and the activities to be performed under this Agreement.
  - (b) It is the intention of the Parties that the interpretation of the definitions related to this <u>Article 5</u> shall be in accordance with U.S. GAAP consistently applied in accordance with the applicable Party's then current practices. A Party shall promptly make the appropriate adjustments to the financial information it supplies under this Agreement to reflect changes to the provisions, including reasonable detail underlying the adjustment, in reporting results of operation.
  - (c) Furthermore, for any costs or expenses in connection with the performance of its activities hereunder, which are reimbursable by one Party or subject to cost-sharing between the Parties, if such costs or expenses consist of payments made by either Party to a Third Party, they shall be charged hereunder at the respective Party's actual out-of-pocket cost.

(d) Notwithstanding anything in this Agreement to the contrary, each Party shall be solely responsible for all travel costs for such Party's and its Affiliates' and agents' employees incurred in connection with the performance of such Party's obligations hereunder, and no travel-related expenses incurred by either Party in connection with Development activities hereunder shall be included in Development Costs or Operating Costs.

### 5.5.3. <u>Cost Reporting</u>.

- (a) <u>Development Costs</u>. No later than [\* \* \*] Business Days after the end of each Contract Quarter, each Party shall report to the other Party an estimate of its North American and European Development Costs (including any Third Party Intellectual Property Costs that are deemed Development Costs) and Patent Procurement Costs (for which reimbursement is required pursuant to <u>Section 8.2.4</u>). Furthermore, as soon as practicable after the end of each Contract Quarter, but in any event no later than [\* \* \*] days after the end of each Contract Quarter, each Party shall report to the other Party actual North American and European Development Costs and Patent Procurement Costs (for which reimbursement is required pursuant to <u>Section 8.2.4</u>). Notwithstanding the foregoing, Celgene shall have no obligation to report to Acceleron Celgene's estimated or actual North American and European Development Costs incurred on or after January 1, 2013, though Celgene will continue to report any Patent Procurement Costs as described in this <u>Section 5.5.3(a)</u>.
- (b) Results of Operations in North America. No later than [\* \* \*] Business Days after the end of each Contract Quarter, each Party shall report to the other Party an estimate of such Party's results of operations in North America, as applicable, related to the following: (i) aggregate gross invoice prices of all units of Licensed Product sold; (ii) sales returns and allowances; (iii) Net Sales; (iv) number of units sold; and (v) in the case of Acceleron, all Sales Force Costs of Acceleron and any other Operating Costs of Acceleron in North America that have been approved under the Commercialization Plan/Budget (collectively, the "Acceleron NA Operating Costs"). Furthermore, as soon as practicable after the end of each Contract Quarter, but in any event no later than [\* \* \*] days after the end of each Contract Quarter, each Party shall report to the other Party actual results of operations in North America, as described in the prior sentence.

#### 5.5.4. Expense Limitations.

(a) Expenses charged by either Party as North American and European Development Costs for any Contract Year shall not exceed [\* \* \*] percent [\* \* \*] of the amount included for the total expenditure in the then-current Development Plan/Budget.

- (b) The Acceleron NA Operating Costs for any Contract Year shall not exceed [\* \* \*] percent [\* \* \*] of the amount included for the total expenditure in the then-current Commercialization Plan/Budget.
- (c) If the actual North American and European Development Costs enumerated in the Development Plan/Budget or if the Acceleron NA Operating Costs enumerated in the Commercialization Plan/Budget are expected to vary by more than [\* \* \*] percent [\* \* \*] from the amounts budgeted for expenditure during the Contract Year, the Party responsible for the forecasted variance shall promptly revise the Development Plan/Budget or Commercialization Plan/Budget, as applicable, and submit it in writing, with an explanation of the variance and the reasons therefore, to the other Party. If the Joint Development Committee or Joint Commercialization Committee, as applicable, agrees in writing that the revised budget is acceptable then such revised budget shall be incorporated into the respective Development Plan/Budget or Commercialization Plan/Budget for the remainder of the Contract Year.
- (d) Notwithstanding the foregoing, this <u>Section 5.5.4</u> shall not apply to North American and European Development Costs incurred by Celgene on or after January 1, 2013.
- 5.5.5. Reconciliation Statements. In addition to providing its report of North American and European Development Costs and Acceleron NA Operating Costs, as specified in Section 5.5.3, within [\* \* \*] days following the end of a Contract Quarter, each Party will provide a summary report of North American and European Development Costs for the Contract Quarter, and Celgene shall prepare, in consultation with Acceleron, a statement (the "Reconciliation Statement"); provided that Celgene shall have no obligation to report to Acceleron Celgene's North American and European Development Costs incurred on or after January 1, 2013. Each Reconciliation Statement shall show Celgene's calculations of costs to be shared by both Parties pursuant to this Section 5.5 and the cash settlement required. Payments required pursuant to Reconciliation Statements shall be made by Acceleron or Celgene in the manner set forth in Section 5.7.5.

#### 5.6 Royalties.

- 5.6.1. <u>Royalty Percentages</u>. For sales of Licensed Products in the Territory, Celgene shall retain all amounts received for such sales; <u>provided</u> that Celgene shall pay to Acceleron the following royalty payments on a Licensed Product-by-Licensed Product basis during the applicable Royalty Term:
  - (a) [\* \* \*] percent [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is less than or equal to [\* \* \*];

- (b) [\* \* \*] percent [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is greater than [\* \* \*] and less than or equal to [\* \* \*]; and
- (c) [\* \* \*] percent [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is greater than [\* \* \*];

<u>provided further</u> that the applicable thresholds above will be determined on a region-by-region basis with each of the following areas of the Territory treated as one region: (i) North America and (ii) the rest of the Territory.

- 5.6.2. <u>Cumulative Royalties</u>. The obligation to pay royalties under this Agreement shall be imposed only once with respect to a single unit of a Licensed Product regardless of how many Valid Claims included within Acceleron Patent Rights would, but for this Agreement, be infringed by the Manufacture or Commercialization of such Licensed Product.
- 5.6.3. Adjustment in Royalty Rates.
  - (a) <u>Know-How Only or Generic Competition</u>. On a country-by-country and Licensed Product-by-Licensed Product basis, upon the earlier to occur of (i) the date on which the offering for sale, selling, making, having made, using or importing of a Licensed Product is no longer covered by a Valid Claim of an Acceleron Patent Right in such country (but such Manufacture, use or sale of a Licensed Product continues to be covered by Acceleron Know-How) or (ii) the date on which in such country there are one or more Generic Products, then the royalty percentage applicable to Net Sales of such Licensed Product under <u>Section 5.6.1</u> for such Licensed Product in such country shall be reduced by fifty percent (50%) for the remainder of the Royalty Term.
  - (b) <u>Celgene Third Party Licenses</u>. In the event that one or more licenses to Third Party Intellectual Property are required by Celgene to offer for sale, sell, make, have made, use or import Licensed Compounds or Licensed Products in the Field in the Territory without infringing the Third Party Intellectual Property (including claims of a pending patent application that are reasonably expected to issue), then Celgene may offset fifty percent (50%) of the amount of commercially reasonable royalties or other payments payable by Celgene to such Third Party (or paid or reimbursed by Celgene pursuant to <u>Section 5.6.3(c)</u>) with respect to a particular Licensed Product against amounts Celgene is obligated to pay Acceleron under <u>Section 5.4</u> or <u>Section 5.6.1</u> for such Licensed Product, <u>provided</u> that in no such event shall any such offset reduce by more than fifty percent (50%) the payments otherwise due to Acceleron in particular Contract Years; <u>provided further</u> that on a Licensed Product-by-Licensed Product basis, any Third Party royalty payments that are not credited against royalties or sales milestones paid to Acceleron in the Contract Year in which they were accrued shall be carried forward and credited against royalties or sales milestones payable

to Acceleron in the subsequent Contract Year(s) hereunder until such royalty credits are completely expended. The calculation of the royalty reduction under this Section 5.6.3(b) shall be conducted on a country-by-country and Licensed Product-by-Licensed Product basis. Celgene shall provide Acceleron with notice and a copy of each such license, and any modification or termination thereof, promptly (and in any event within [\* \* \*] days after such agreement has been fully executed) after execution of such license, modification or termination; provided that any such copy may be redacted to remove any confidential, proprietary or competitive information of Celgene or its Sublicensee, but such copy shall not be redacted to the extent that it impairs Acceleron's ability to ensure compliance with this Agreement. With respect to any license entered into by Celgene to Third Party Intellectual Property, Celgene shall use Commercially Reasonable Efforts to ensure that such Third Party Intellectual Property is sublicensable to Acceleron to the extent required under this Agreement.

Third Party Intellectual Property. Acceleron shall not enter into an agreement with a Third Party to obtain a license under Third Party Intellectual Property that solely covers the offering for sale, selling, making, having made. using or importing Licensed Compounds or Licensed Products in the Field in the Territory (including rights of a pending patent application that are reasonably expected to issue) without first offering Celgene the opportunity to contact such Third Party regarding entering into such agreement directly. With respect to Third Party Intellectual Property that covers the offering for sale, selling, making, having made, using or importing Licensed Compounds or Licensed Products in the Field in the Territory but also covers Acceleron's other products or compounds, Acceleron shall notify the Joint Development Committee or Joint Commercialization Committee, as applicable, of the Third Party Intellectual Property (a "Third Party Intellectual Property Notice"). With respect to such a license for such Third Party Intellectual Property that covers the offering for sale, selling, making, having made, using or importing Licensed Compounds or Licensed Products in the Field in the Territory. Acceleron may enter into the license for such Third Party Intellectual Property; provided that, if the Joint Development Committee or Joint Commercialization Committee, as applicable, determines that such Third Party Intellectual Property should be part of the Collaboration, then the following shall apply: (i) Acceleron shall keep Celgene fully informed of the status of the negotiations with the Third Party and provide Celgene with copies of all draft agreements; (ii) Celgene may provide comments and suggestions with respect to the negotiation of the agreement with the Third Party, and Acceleron shall reasonably consider all comments and suggestions reasonably recommended by Celgene; (iii) Acceleron shall use Commercially Reasonable Efforts to ensure that such Third Party Intellectual Property is sublicensable to Celgene in accordance with the terms of this Agreement, treating (unless otherwise agreed by the Parties) the Third Party Intellectual Property as Acceleron Know-How or Acceleron Patent Rights hereunder and treating the agreement licensing such the Third Party Intellectual Property in the same way as

the Salk License (including as provided in Section 4.5.), except for payment obligations; provided that, if Acceleron is not able to obtain a license from such Third Party that is sublicensable in accordance with this clause (iii), then Acceleron shall promptly so notify Celgene and shall exclude from any such license that Acceleron obtains the offering for sale, selling, making, having made, using or importing Licensed Compounds or Licensed Products in the Field in the Territory, and (iv) the Parties shall allocate the Third Party Intellectual Property Costs, unless otherwise agreed, as follows: (x) the Parties shall determine in good faith an allocation of upfront payments and intellectual property acquisition fees paid to any such Third Party with respect to Licensed Compounds or Licensed Products to be treated as either Development Costs or Operating Costs, (v) development milestone payments owed to such Third Party that are required to be paid as a result of the Development of Licensed Compounds or Licensed Products shall be treated as Development Costs, and (z) sales milestone payments and royalties owed to such Third Party that are required to be paid as a result of sales of Licensed Products shall be treated as royalties paid to Third Parties pursuant to Section 5.6.3(b). In the event that Acceleron delivers to Celgene a Third Party Intellectual Property Notice and pursues a license to the applicable Third Party Intellectual Property from such Third Party, Celgene will not directly or indirectly (other than through Acceleron pursuant to this Agreement) pursue a license to such Third Party Intellectual Property unless (1) Acceleron decides to not pursue a license to such Third Party Intellectual Property that covers a Licensed Compound or Licensed Product (in which event, Acceleron will promptly notify Celgene of such decision), (2) Acceleron notifies Celgene that Acceleron is not able to obtain a sublicensable license in accordance with clause (iii) of the third sentence of this Section, or (3) Celgene was already in discussions with such Third Party prior to Celgene's receipt of the Third Party Intellectual Property Notice regarding licensing such Third Party Intellectual Property.

- (d) <u>Buy-Down</u>. Celgene may elect to reduce the royalty percentages set forth in <u>Section 5.6.1</u> and in Section 5.6.1 of that certain Collaboration, License and Option Agreement entered into by the Parties as of August 2, 2011 (as amended from time to time in accordance with its terms, the "**ACE-536 Agreement**") by (i) providing Acceleron with written notice of Celgene's election on or before January 1, 2013 and (ii) paying to Acceleron a one-time payment of \$25 million (the "**Buy-Down Payment**") within 30 days of the date of such notice. Immediately upon payment by Celgene of the Buy-Down Payment, the royalty payments to be paid by Celgene to Acceleron under <u>Section 5.6.1</u> of this Agreement shall be replaced with the following royalty payments:
  - (i) [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is less than or equal to [\* \* \*];

- (ii) [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is greater than [\* \* \*] and less than or equal to [\* \* \*]; and
- (iii) [\* \* \*] of annual Net Sales in each region of the Territory during a Contract Year for that portion of the annual Net Sales in such region that is greater than [\* \* \*];

provided that the applicable thresholds above will be determined on a region-by-region basis with each of the following areas of the Territory treated as one region: (x) North America and (y) the rest of the Territory. Any adjusted royalty payment made under this Section 5.6.3(d) shall be subject to reduction pursuant to Section 5.6.3(a) through Section 5.6.3(c) (and all references to Section 5.6.1 in such sections shall be deemed to be references to this Section 5.6.3(d) if applicable). The payment of the Buy-Down Payment shall also have the effects set forth in Section 5.6.3(a) of the ACE-536 Agreement.

5.6.4. Reports and Royalty Payments. Within [\* \* \*] days after the beginning of each Contract Quarter during the Royalty Term, Celgene shall deliver to Acceleron a report setting forth for the previous Contract Quarter the following information on a Licensed Product-by-Licensed Product and country-by-country basis in the Territory: (a) the gross sales and Net Sales of Licensed Product, (b) the number of units sold by Celgene, its Affiliates or Sublicensees, (c) the basis for any adjustments to the royalty payable for the sale of each Licensed Product, and (d) the royalty due hereunder for the sales of each Licensed Product (the "Royalty Report"). The total royalty due for the sale of Licensed Products during such Contract Quarter shall be remitted at the time such report is made. No such reports or royalty shall be due for any Licensed Product before the First Commercial Sale of such Licensed Product.

### 5.7 Payment Provisions Generally.

- 5.7.1. Taxes and Withholding. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in Section 5.6., Celgene shall make such withholding payments as required and subtract such withholding payments from the payments set forth in Section 5.6. Celgene shall submit appropriate proof of payment of the withholding taxes to Acceleron within a reasonable period of time. At the request of Acceleron, Celgene shall give Acceleron such reasonable assistance, which shall include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable Acceleron to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and shall upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.
- 5.7.2. Payment and Currency Exchange.

- (a) All amounts (including all costs sharing) payable and calculations hereunder shall be in United States dollars and shall be paid by bank wire transfer in immediately available funds to such bank account as may be designated in writing by Acceleron or Celgene, as applicable, from time to time. Whenever for the purposes of calculating the royalties payable under Section 5.6 or the costs payable under Section 5.5 conversion from any foreign currency shall be required, all amounts shall first be calculated in the currency of sale or currency of incurrence and then converted into United States dollars by applying the average monthly rate of exchange listed in the New York edition of *The Wall Street Journal* for the final month of the applicable Contract Ouarter.
- (b) Where royalty amounts are due for Net Sales in a country where, for reasons of currency, tax or other regulations, transfer of foreign currency out of such country is prohibited, Celgene has the right to place Acceleron's royalties in a bank account in such country in the name of and under the sole control of Acceleron; provided, however, that the bank selected be reasonably acceptable to Acceleron and that Celgene inform Acceleron of the location, account number, amount and currency of money deposited therein. After Acceleron has been so notified, those monies shall be considered as royalties duly paid to Acceleron and will be completely controlled by Acceleron.
- (c) When in any country in the Territory the law or regulations prohibit both the transmittal and the deposit of royalties on sales in such country, royalty payments due on Net Sales shall be suspended for as long as such prohibition is in effect and as soon as such prohibition ceases to be in effect, all royalties that Celgene would have been under an obligation to transmit or deposit but for the prohibition shall forthwith be deposited or transmitted, to the extent allowable.
- 5.7.3. Records . Each Party shall keep and maintain accurate and complete records which are relevant to costs, expenses, sales and payments throughout the Territory used to determine payments to be made under this Agreement, and such records shall be maintained for a period of three (3) years from creation of individual records for examination at the other Party's expense by an independent certified public accountant selected by the other Party as described in Section 5.7.4 . A Party's right to complete a final audit upon termination or expiration of this Agreement shall expire one year after such termination or expiration. Any records or accounting information received from the other Party shall be Confidential Information of the disclosing Party for purposes of Article 9 of this Agreement. Results of any such audit shall be provided to both Parties, subject to Article 9 of this Agreement.

#### 5.7.4. Audits and Interim Reviews.

(a) Subject to the provisions of <u>Section 5.7.3</u>, either Party may request that a nationally recognized, independent accounting firm to be mutually agreed upon by the Parties, which is not either Party's independent accounting firm, perform an audit or interim review of the other Party's books as they relate to this

Agreement in order to express an opinion regarding such Party's accounting for revenues, costs and expenses, as applicable, under this Agreement. Such audits or review shall be conducted at the expense of the requesting Party.

- Upon [\* \* \*] Business Days' prior written notice from a Party (the "Auditing Party"), the other Party (the " **Audited Party** ") shall permit such accounting firm to examine the relevant books and records of the Audited Party, including any Affiliates, as may be reasonably necessary to verify the reports and information submitted by the Audited Party and the accuracy of any Royalty Report or Reconciliation Statement. An examination by a Party under this Section 5.7.4 (whether of the Audited Party or its Affiliates) shall [\* \* \*] and shall be limited to the pertinent books and records for any Contract Year ending not more than [\* \* \*] months before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination shall be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement with terms that are not inconsistent with the terms of this Agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide both Celgene and Acceleron a written report disclosing whether the reports submitted by the Audited Party are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Auditing Party. If the accountant determines that, based on errors in the reports so submitted, any report prepared in accordance with this Agreement is incorrect, the Parties shall promptly revise the report and the associated Royalty Report or Reconciliation Statement and any additional amount owed by one Party to the other shall be paid within [\* \* \*] days after receipt of the accountant's report, along with interest as provided in Section 5.7.5; provided, however, that no such interest shall be payable if the errors leading to the Royalty Report or Reconciliation Statement being incorrect were in the reports provided by the Party to receive such additional amount. Additionally, if the accountant determines that the reports submitted by the Audited Party misstate the Audited Party's share of costs by more than [\* \*\* percent [\* \* \*] to the Auditing Party's detriment, the Audited Party shall reimburse the Auditing Party for the expenses incurred by the Auditing Party in conducting the audit. In the event of any sublicense or transfer of rights with respect to Licensed Compounds or Licensed Products by a Party under this Agreement, the sublicensor or transferor shall provide for audit rights by the other Party to this Agreement in accordance with this Section 5.7.4.
- 5.7.5. <u>Payments Between the Parties</u>. There shall be a cash settlement between the Parties no later than [\* \* \*] days after the end of each Contract Quarter. In the event that (a) any payment hereunder (including any royalty payment due by Celgene to Acceleron under this Agreement) is made after the date specified in the preceding sentence (other than the extent that a payment that is the subject of a good faith dispute between the Parties that has been

outstanding for no more than [\* \* \*] Business Days), and (b) such payment is overdue by more than [\* \* \*] Business Days, the paying Party shall pay interest to the other Party at the lesser of (i) the annualized interest rate at the three (3) month LIBOR plus one percent (1%) or (ii) the highest rate permitted by applicable law from the date that such additional amount should have first been paid.

#### Article 6

#### **EXCLUSIVITY**

#### 6.1 **Prohibitions**.

- 6.1.1. If Celgene irrevocably forfeits its rights to develop an Option Compound pursuant to Article 7 (a "Forfeited Option Compound"), then, during the Agreement Term, neither Acceleron nor any of its Affiliates, directly or indirectly with a Third Party, shall, with any such Forfeited Option Compound or product containing any such Forfeited Option Compound (i) conduct any clinical study whose primary endpoint is [\* \* \*] unless such clinical study is required by any Regulatory Authority, in which event, the provisions of clauses (ii) and (iii) of this Section shall apply notwithstanding the conduct of such clinical trials, (ii) seek or obtain Regulatory Approval for such product indicated for [\* \* \*], or (iii) market or promote such product for the [\* \* \*].
- 6.1.2. During the Agreement Term, neither Acceleron nor any of its Affiliates, directly or indirectly with a Third Party, shall, with any product containing [\* \* \*]: (i) conduct any clinical study whose primary endpoint is [\* \* \*] unless such clinical study is required by any Regulatory Authority, in which event, the provisions of clauses (ii) and (iii) of this Section shall apply notwithstanding the conduct of such clinical trials, (ii) seek or obtain Regulatory Approval for such product indicated for [\* \* \*], or (iii) market or promote such product for [\* \* \*]. Notwithstanding the foregoing, neither Acceleron nor its Affiliates shall be restricted in any way, directly or indirectly, from developing or commercializing [\* \* \*] for [\* \* \*].
- 6.1.3. During the Agreement Term, neither Party nor any of its Affiliates, directly or indirectly with a Third Party, shall, whether pursuant to this Agreement or otherwise, with any product containing [\* \* \*] (i) conduct any clinical study whose primary endpoint is [\* \* \*] unless such clinical study is required by any Regulatory Authority, in which event, the provisions of clauses (ii) and (iii) of this Section shall apply notwithstanding the conduct of such clinical trials, (ii) seek or obtain Regulatory Approval for such product indicated for [\* \* \*], or (iii) market or promote such product for [\* \* \*].
- 6.1.4. In any Third Party license, development, research, collaboration, commercialization or similar agreement with respect to an Option Compound, [\* \* \*], [\* \* \*], or other product, as applicable, each Party and its Affiliates shall include restrictions on such Third Party's use of the Party's or its Affiliates intellectual property that are the same as those on the Parties and its Affiliates set forth in this Section 6.1. For clarity, the prohibition on conducting activities directly or indirectly with a Third Party includes a prohibition on

providing any support for an external or academic investigator or site for conducting a clinical study.

- 6.1.5. During the Agreement Term, neither Acceleron nor any of its Affiliates, directly or indirectly with a Third Party, shall, with any product: (a) conduct any clinical study whose primary endpoint is Use in Anemia unless such clinical study is required by any Regulatory Authority, in which event, the provisions of clauses (b) and (c) of this Section shall apply notwithstanding the conduct of such clinical trials; (b) seek or obtain Regulatory Approval for such product indicated for Use in Anemia; or (c) market or promote such product for Use in Anemia. Notwithstanding the foregoing, the provisions of this Section 6.1.5 shall not apply to Acceleron or its Affiliates to the extent of conducting the activities required to fulfill Acceleron's obligations hereunder or under the ACE-536 Agreement.
- 6.1.6. Notwithstanding the foregoing, the provisions of Section 6.1.5 (or the provisions in Section 6.1.4 related thereto) shall not apply to the activities of [\* \* \*], its sublicensees (of the rights granted by Acceleron under the [\* \* \*] Agreement), Affiliates, successors and/or assigns, or to Acceleron and its Affiliates fulfilling their respective obligations to [\* \* \*], its sublicensees (of the rights granted by Acceleron under the [\* \* \*] Agreement), Affiliates, successors and/or assigns, with respect to any and all compounds covered by the rights granted by Acceleron prior to the Effective Date to [\* \* \*] pursuant to the [\* \* \*] by and between Acceleron and [\* \* \*], as amended from time to time in accordance with its terms (the "[\* \* \*] Agreement"), so long as the [\* \* \*] Agreement continues to remain in effect; provided that (a) any future rights granted to [\* \* \*] (including by any amendment or modification of the [\* \* \*] Agreement) shall be subject to the provisions of Section 6.1.5 (or the provisions in Section 6.1.4 related thereto); (b) if Acceleron agrees to collaborate with [\* \* \*] on the identification, research and development of any product or compound (other than [\* \* \*] (as each term is defined in the [\* \* \*] Agreement as of the date hereof)) shall be subject to the provisions of Section 6.1.5 (or the provisions in Section 6.1.4 related thereto). Acceleron represents and warrants to Celgene that neither [\* \* \*] nor [\* \* \*] is a [\* \* \*] (as defined in the [\* \* \*] Agreement as of the date hereof).
- 6.1.7. For purposes of this Article 6, each of the following terms shall have the meanings set forth below:
  - (a) "Anemia" means anemias, disorders of red blood cells and disorders of erythropoiesis. For the avoidance of doubt, "Anemia" includes any decrease in function and quality of red blood cells, or any deficiency in the function of red blood cells, or less than the normal quantity of hemoglobin in the blood, or any deficiency in the function of hemoglobin.
  - (b) "Use in Anemia" means the treatment, prevention, modulation or diagnosis of Anemia, including any companion diagnostic or biomarkers associated with the treatment, prevention, modulation or diagnosis of Anemia. For example, treatment includes increase of hematocrit, hemoglobin, or red blood cells.
- 6.2 Third Party Acquisitions.

- 6.2.1. <u>Bone-Loss, Anti-Cancer, and Muscle Loss Exclusivities</u>. The provisions of <u>Sections 6.1.1</u>, <u>6.1.2</u> and <u>6.1.3</u> (and the provisions of <u>Section 6.1.4</u> related thereto) are not intended to apply to any activity otherwise prohibited by such sections if a Party's involvement in such prohibited activity results from such Party's acquisition by a Third Party (either directly or through any Affiliate, whether by merger, purchase of assets or equity, or otherwise), but only if (i) such Third Party, prior to such acquisition or merger, was already engaged in such prohibited activity (the "**Third Party Activity**"), and (ii) no Celgene Technology, Acceleron Technology, or Joint Technology is used in connection with such Third Party Activities.
- 6.2.2. <u>Anemia Exclusivity</u>. The provisions of <u>Section 6.1.5</u> (and the provisions of <u>Section 6.1.4</u> related thereto) do not apply to any activity otherwise prohibited by <u>Section 6.1.5</u> if Acceleron's involvement or the involvement of any of its Affiliates in such prohibited activity results from or occurs subsequently to the acquisition of Acceleron by a Third Party (either directly or through any Affiliate, whether by merger, purchase of assets or equity, or otherwise), but only if:
  - (a) no Celgene Technology, Acceleron Technology or Joint Technology is used in connection with such Third Party activities;
  - (b) no Patent Rights Controlled by Acceleron or its Affiliates immediately prior to the acquisition or Patent Rights developed based on the Know-How described in <u>Section 6.2.2(c)</u> is used in connection with such Third Party activities:
  - (c) no Know-How relating to any TGF Beta superfamily compounds (including ligand, binding partner of a ligand, or a receptor of any such compounds) Controlled by Acceleron or their Affiliates prior to the acquisition or further Know-How relating to such TGF Beta superfamily compound developed based on such existing Know-How is used in connection with such Third Party activities for the longer of seven (7) years from the Effective Date or five (5) years from the date of the acquisition of Acceleron by a Third Party; and
  - (d) no Know-How Controlled by Celgene or its Affiliates that is provided, prior to the acquisition, to Acceleron pursuant to this Agreement or developed based on such existing Know-How is used in connection with such Third Party activities.
  - 6.2.3 <u>Acquisitions of Acceleron by Certain Third Parties</u>. Subsequent to an acquisition of Acceleron by a designated Third Party set forth in Schedule 6.2.3, the following shall apply:
    - (a) Notwithstanding anything to the contrary in <u>Section 2.1.1</u>, Celgene shall be solely responsible for conducting all Development activities of each Licensed Compound or related Licensed Product in the Field;

- (b) Notwithstanding anything to the contrary in <u>Section 2.4.1</u>, Celgene may, within ninety (90) days, provide Acceleron with written notice, at Celgene's sole discretion, instructing Acceleron to cease all Manufacturing activities hereunder;
- (c) Celgene's obligation to provide reports under <u>Article 2</u> and <u>Article 3</u> shall cease; <u>provided</u>, <u>however</u>, that Celgene shall continue to provide reports under <u>Section 2.9.3</u> (which reports will be respect to the entire Territory, not just outside North American and Europe) and semiannual reports regarding Development of Licensed Products; and
- (d) The Joint Development Committee and Joint Commercialization Committee shall each be dissolved, in which event, (i) Celgene, in its own sole discretion, shall make all decisions, and take all actions, ascribed to the Joint Development Committee or Joint Commercialization Committee pursuant to and subject to the remaining applicable terms and conditions of this Agreement (and, in furtherance thereof, all applicable references to Joint Development Committee or Joint Commercialization Committee hereunder shall be deemed to be references to Celgene); and (ii) Celgene's obligations under Article 2 and Article 3 (x) to report or share with Acceleron the Development Plan/Budget and Commercialization Plan/Budget, and (y) to consult with Acceleron or permit Acceleron to participate with respect to Development, Commercialization, or regulatory matters shall cease; provided that, to the extent that Acceleron elects or continues to co-promote any Licensed Product pursuant to Section 2.7, Celgene shall continue to comply with the obligations of such section with respect to such co-promotion.
- Acquisitions of Third Parties . The provisions of this Article 6 do not apply to any activity otherwise prohibited by this Article 6 if a Party's involvement or the involvement of any of its Affiliates in such prohibited activity results from such Party's acquisition (either directly or through any Affiliate, whether by merger, purchase of assets or equity, or otherwise) of all or substantially all of the business or assets of a Third Party, but only if (i) such Third Party, prior to such acquisition or merger, was already engaged in such prohibited activity (the "Acquired Party Activity"), and (ii) such acquiring Party shall, within thirty (30) days after the date of such Party's consummation of such acquisition, notify the other Party of such acquisition and comply with the other provisions of this Section 6.3. Following consummation of such an acquisition, the acquiring Party shall, at its option, either (i) use good faith efforts to identify a Third Party purchaser to whom such Party will divest its interest in the Acquired Party Activity and to enter into a definitive agreement with such Third Party for such divestiture as soon as reasonably practicable under the circumstances, but such divestiture must be completed no later than twelve (12) months after the closing of such Party's acquisition of the Acquired Party Activity, or (ii) promptly discontinue such Acquired Party Activity; provided that, notwithstanding which option is chosen, such divesture or discontinuation must be accomplished no later than twelve (12) months after the closing of such Party's acquisition of the Acquired Party Activity. During the time period following the consummation of an acquisition covered by this Section 6.3 through

the divestiture or discontinuation of the Acquired Party Activity, the acquiring Party shall not use any Celgene Technology, Acceleron Technology, or Joint Technology in connection with such Acquired Party Activities. So long as the acquiring Party divests of, or discontinues, the Acquired Party Activity in accordance with this Section 6.3, such acquisition shall not be deemed a violation of this Article 6. Notwithstanding anything to the contrary in this Article 6, this Section 6.3 shall not apply to any activity of Acceleron, its Affiliates or a Third Party acquirer of Acceleron subsequent to the acquisition of Acceleron by a Third Party (either directly or through any Affiliate, whether by merger, purchase of assets or equity, or otherwise); provided that the provisions of Section 6.2 shall continue to apply to Acceleron, its Affiliates, a Third Party acquirer of Acceleron and any Third Party acquired by Acceleron (either directly or through any Affiliate, whether by merger, purchase of assets or equity, or otherwise).

6.4 **Termination of ACE-536 Agreement**. In the event of termination of the ACE-536 Agreement by Acceleron for cause under Section 10.2.1 of the ACE-536 Agreement, Acceleron's use of any "Licensed Compounds" or "Licensed Products" under the ACE-536 Agreement shall no longer be subject to the exclusivity provisions of <u>Article 6</u> of this Agreement that relate to a product for Use in Anemia; <u>provided</u> that, for the avoidance of doubt, any other exclusivity provisions of this Agreement shall continue to apply. For the avoidance of doubt, termination of the ACE-536 Agreement under Section 10.3 or Section 10.4 of the ACE-536 Agreement or expiration of the ACE-536 Agreement shall not affect any rights or obligations of the Parties under this Agreement, and Acceleron's use of any "Licensed Compounds" or "Licensed Products" under the ACE-536 Agreement shall continue to be subject to any exclusivity provisions of this Agreement.

#### Article 7

#### **OPTION PROGRAM**

- 7.1 **Conduct of Option Compound Programs**. Acceleron shall be solely responsible for, and shall pay all costs associated with, managing all Development, and Manufacturing activities for each Option Compound through the completion of Phase 2A Clinical Trials for each Option Compound in its sole discretion. Unless Celgene forfeits its right to an Option Compound pursuant to Section 7.2, for a period of [\* \* \*] from the Effective Date, Celgene shall have the exclusive option to such Option Compound in accordance with the terms hereof, and Acceleron shall not grant any Third Party any rights to such Option Compound.
- 7.2 **Option Program Payments**. With respect to products containing [\* \* \*] Antibodies, [\* \* \*] Antibodies, or [\* \* \*] Antibodies, Acceleron shall provide Celgene with written notice after the earliest date on which the corresponding milestone event has first been achieved with respect to the applicable Option Compound. In the event that Celgene makes each payment set forth in the chart below, through and including the payment due upon completion of a Phase 2A Clinical Trial, (the "**Option Program Payments**") with respect to products containing [\* \* \*] Antibodies, [\* \* \*] Antibodies, or [\* \* \*] Antibodies no later than [\* \* \*] days (or [\* \* \*] days in the case of the third milestone event related to delivery of the results of the Phase 2A Clinical Trial) after Celgene's receipt of notice from Acceleron that the corresponding milestone event has first been achieved with respect to the applicable Option Compound, (i) the definition of "Licensed

Compound" shall automatically be deemed, effective as of the date of receipt of the last applicable Option Program Payment by Acceleron, to include [\* \* \*] Antibodies, [\* \* \*] Antibodies, or [\* \* \*] Antibodies, as applicable, and (ii) the definition of "Acceleron Patent Rights" shall automatically be deemed, effective as of the date of receipt of the last applicable Option Program Payment by Acceleron, to include the [\* \* \*] Antibody Patent Rights, [\* \* \*] Antibody Patent Rights, or [\* \* \*] Antibody Patent Rights, as applicable. In the event that Celgene does not make each Option Program Payment for a particular Option Compound within the required time period, Celgene shall fully and irrevocably forfeit any right to develop such Option Compound, and all right, title and interest in such Option Compound shall remain the property of Acceleron. For clarity, the making of any Option Program Payment is solely within the discretion of Celgene.

<u>Milestone Event</u>	-	Payment for Each Option Compound		
	[* * *]	[* * *]	[* * *]	
[* * *]	\$[* * *]	\$[***]	\$[* * *]	
[* * *]	\$[***]	\$[* * *]	\$[* * *]	
[* * *]	\$[* * *]	\$[* * *]	\$[* * *]	

For clarity, each Option Program Payment set forth in this <u>Section 7.2</u> shall be paid only once for each Option Compound, regardless of whether more than one Clinical Trial may be conducted for such Option Compound.

7.3 **Updates; Reports** . For so long as Celgene's option under this <u>Article 7</u> remains in place, Acceleron shall provide Celgene with regular updates no less than once a [\* \* \*] on the results of the Option Compound Development program. Such updates shall be conducted by telephone or video-conference, and prior to each such update, Acceleron shall provide Celgene with a written summary of the activities conducted under the Option Compound program for the preceding [\* \* \*] and supporting data related thereto. Celgene shall have the right to reasonably request and to receive in a timely manner clarifications and answers to questions with respect to such reports.

#### **Article 8**

#### INTELLECTUAL PROPERTY PROTECTION AND RELATED MATTERS

### 8.1 Salk Patent Rights.

8.1.1. Celgene acknowledges that the Acceleron Patent Rights listed on <u>Schedule 8.1</u> (the "Salk Patent Rights") have been licensed by Acceleron from Salk pursuant to the Salk License.

- 8.1.2. Acceleron acknowledges that, pursuant to the Salk License, it has the below rights with respect to the Salk Patent Rights and agrees to keep Celgene fully informed of these rights, as well as provide to Celgene all information and copies of documents received from Salk or its patent counsel relating to the Salk Patent Rights:
  - (a)

    The right to proceed with the Prosecution of the Salk Patent Rights in the event that Salk does not exercise its rights to do so;
  - (b)
    The right, in certain circumstances, to review any patent documents prior to filing and to provide comments and suggestions for revision thereof; and
  - (c)
    The right, in certain circumstances, to initiate legal proceedings against third parties for infringement of the Salk Patent Rights.
- 8.1.3. In the event that Acceleron is permitted to proceed with Prosecution, provide comments or suggestions to patent documents, or initiate legal proceedings with respect to the Salk Patent Rights, then such Salk Patent Rights shall be treated in the same manner as other Acceleron Patent Rights under this <u>Article 8</u>, and Acceleron shall exercise all such rights with respect to the Salk Patent Rights pursuant to the instructions of Celgene, if Celgene is given the first right to act under this <u>Article 8</u>.

#### 8.2 Prosecution of Patent Rights .

8.2.1. Other Acceleron Patent Rights and Joint Patent Rights. The following terms shall apply to all Acceleron Patent Rights owned by Acceleron and all Joint Patent Rights.

#### (a) Primary Responsibility.

(i) Acceleron, through counsel of its choosing, shall have primary responsibility for and control over obtaining, filing, prosecuting (including any interferences, reissue proceedings, re-examinations, oppositions, and revocations), and maintaining (collectively, "Prosecuting" or, when used as a noun, "Prosecution") throughout the Territory the Acceleron Patent Rights (and, for clarity, will be the "Prosecuting Party" with respect to the Acceleron Patent Rights), and Celgene shall cooperate with Acceleron in regard thereto. Celgene, through counsel of its choosing, shall have primary responsibility for and control over Prosecuting throughout the Territory the Joint Patent Rights (and, for clarity, will be the "Prosecuting Party" with respect to the Joint Patent Rights), and Acceleron shall cooperate with Celgene in regard thereto. If the Prosecuting Party elects to abandon (except in the course of Prosecution to pursue such subject matter or claim in a continuing application) any subject matter or claim that (x) relates to any of the rights licensed to the Non-Prosecuting Party

hereunder or (y) is filed or requested to be filed by a Prosecuting Party at the request of the Non-Prosecuting pursuant to Section 8.2.1(a)(ii), the Prosecuting Party shall so notify the Non-Prosecuting Party promptly (but no less than [\* \* \*] prior to any deadlines for Prosecution) in writing of its intention in good time to enable the Non-Prosecuting Party to meet any deadlines by which an action must be taken to preserve any such rights in such subject matter or claim, and the Non-Prosecuting Party shall be entitled to acquire control of Prosecuting such subject matter or claim and be deemed the Prosecuting Party with respect thereto.

- (ii) Notwithstanding the foregoing, the Prosecuting Party's choice of outside patent counsel shall be reasonably acceptable to the Non-Prosecuting Party, and the Prosecuting Party shall keep the Non-Prosecuting Party fully informed of Prosecution and provide the Non-Prosecuting Party with copies of material correspondence (including applications, office actions, responses, etc.) relating to Prosecution of any Patent Rights being Prosecuted by such Prosecuting Party. The Non-Prosecuting Party may provide comments and suggestions with respect to any material actions to be taken by the Prosecuting Party, and the Prosecuting Party shall reasonably consider all comments and suggestions and shall take all Prosecution actions reasonably recommended by the Non-Prosecuting Party. The Prosecuting Party shall consult with the Non-Prosecuting Party before taking any action that would have a material adverse impact on the scope of claims within the Acceleron Patent Rights or Joint Patent Rights, as applicable. The Prosecuting Party shall use Commercially Reasonable Efforts to Prosecute additional claims substantially similar to those suggested by the Non-Prosecuting Party, if any, in such jurisdictions of the Territory requested by the Non-Prosecuting Party.
- (iii) In order to facilitate the Non-Prosecuting Party's right to comment, the Prosecuting Party shall provide copies of all such official correspondence and any proposed responses by the Prosecuting Party at least [\* \* \*] days prior to any filing or response deadlines, or within [\* \* \*] Business Days of the Prosecuting Party's receipt of any official correspondence if such correspondence only allows for [\* \* \*] or less to respond, and the Non-Prosecuting Party shall provide any comments promptly and in sufficient time to allow the Prosecuting Party to meet applicable filing requirements. In no event shall the Prosecuting Party be required to delay any submission, filing or response past any deadline that is not extendable. The Prosecuting Party agrees to use Commercially Reasonable Efforts to avoid extension fees, unless agreed to in advance by the Parties, and to take such action as deemed reasonably necessary to preserve pendency of the Patent Rights being Prosecuted by such Prosecuting Party, including the filing of any new or continuing patent

application or payment of any fee necessary to preserve pendency of a pending application.

- (iv) Acceleron covenants and agrees that it shall not grant any Third Party any right to control the Prosecution of the Acceleron Patent Rights or to approve or consult with respect to any Patent Rights licensed to Celgene hereunder, in any case, that is more favorable to the rights granted to Celgene hereunder or otherwise conflicts with Celgene's rights hereunder.
- (b) <u>Common Interest</u>. All information exchanged between the Parties or between the Parties' outside patent counsel regarding Prosecution of the Acceleron Patent Rights or Joint Patent Rights shall be deemed Confidential Information. In addition, the Parties acknowledge and agree that, with regard to such Prosecution of the Acceleron Patent Rights or Joint Patent Rights, the interests of the Parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Acceleron Patent Rights or Joint Patent Rights, including privilege under the common interest doctrine and similar or related doctrines.
- (c) Election Not to Continue Prosecution; Abandonment. If a Prosecuting Party elects (i) not to Prosecute patent applications for the Acceleron Patent Rights or Joint Patent Rights under its Prosecution control in any country, (ii) not to continue the Prosecution of any Acceleron Patent Right or Joint Patent Right under its Prosecution control in a particular country in the Territory, (iii) not to Prosecute patent applications for the Acceleron Patent Rights or Joint Patent Rights under its Prosecution control in a particular country following a written request from the Non-Prosecuting Party to Prosecute in such country, or (iv) not to Prosecute patent applications for the Acceleron Patent Rights or Joint Patent Rights under its Prosecution control reasonably sufficient to protect the Licensed Compounds and Licensed Product following a written notice from the Non-Prosecuting Party setting forth the Non-Prosecuting Party's good faith analysis of the insufficiency of the Prosecuting Party's patent applications, then the Prosecuting Party shall so notify the Non-Prosecuting Party promptly (but no less than 30 days prior to the date that a response is due) in writing of its intention in good time to enable the Non-Prosecuting Party to meet any deadlines by which an action must be taken to establish or preserve any such rights in such patent in such country, and the Prosecuting Party shall permit the Non-Prosecuting Party, should the Non-Prosecuting Party choose to do so, to Prosecute or otherwise pursue such Acceleron Patent Rights or Joint Patent Rights in such country in the Non-Prosecuting Party's own name, and the Prosecuting Party shall cooperate with the Non-Prosecuting Party in regard thereto.

#### 8.2.10.

<u>Celgene Patent Rights</u>. Celgene, through counsel of its choosing, shall have the sole responsibility for and control over Prosecuting throughout the Territory the Celgene Patent Rights, but shall have no obligation to Prosecute such Patent Rights.

#### 8.2.11.

<u>Cooperation</u>. Each Party hereby agrees: (a) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent Prosecution as contemplated by this Agreement; (b) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights that are subject to this Agreement; and (c) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the Prosecution of the other Party's patent applications that are subject to this Agreement.

#### 8.2.4.

#### Patent Procurement Costs.

- (a) All Patent Procurement Costs related to Prosecuting Patent Rights hereunder in Designated Countries shall be shared by the Parties as follows: (a) Patent Procurement Costs relating to the Prosecution of Celgene Patent Rights in Designated Countries or any other countries in the Territory shall be paid for by Celgene, (b) Patent Procurement Costs relating to the Prosecution of Joint Patent Rights in Designated Countries shall be borne equally by the Parties, and (c) Patent Procurement Costs relating to the Prosecution of Acceleron Patent Rights in Designated Countries shall be borne [\* \* \*] percent [\* \* \*] by Acceleron and \* \* \* percent [\* \* \*] by Celgene.
- (b) In the event that Celgene requests that an Acceleron Patent Right or a Joint Patent Right be Prosecuted in any country other than the Designated Countries, then any Patent Procurement Costs relating to such Prosecution of such Acceleron Patent Right or Joint Patent Right, as applicable, in such country shall be deemed a Development Cost. In the event that Acceleron requests that a Joint Patent Right be Prosecuted in any country other than the Designated Countries, then any Patent Procurement Costs relating to such Prosecution of such Joint Patent Right in such country shall be borne [\* \* \*] percent [\* \* \*] by Acceleron and [\* \* \*] percent [\* \* \*] by Celgene.
- (c) Notwithstanding anything else in this <u>Section 8.2.4</u>, any Patent Procurement Costs owed by Acceleron to Salk or any other third party licensor pursuant to an agreement executed by Acceleron prior to the Effective Date (or, with respect to any Option Compound, prior to the date that such Option

Compound is deemed a Licensed Compound in accordance with Article 7) shall be borne solely by Acceleron.

#### 8.3 Enforcement of Patent Rights.

8.3.1. <u>Notification</u>. Each Party shall promptly report in writing to the other Party during the Agreement Term any (a) known or suspected infringement of any Acceleron Patent Rights, Joint Patent Rights or Celgene Patent Rights claiming or relating to Licensed Compounds or Licensed Products, by a Third Party or (b) unauthorized use or misappropriation of any Confidential Information, including Acceleron Technology, Joint Technology and Celgene Technology claiming or relating to Licensed Compounds or Licensed Products, by a Third Party of which it becomes aware and shall provide the other Party with all available evidence supporting such infringement, or unauthorized use or misappropriation.

### 8.3.2. Rights to Enforce.

- Acceleron Technology. The following terms shall apply to all Acceleron Patent Rights (including Acceleron Patent Rights resulting from Acceleron Collaboration IP), Acceleron Improvements and Acceleron Know-How owned by Acceleron and, with respect to other Acceleron Technology (excluding Acceleron Collaboration IP), including Salk Patent Rights, to the extent permitted by the Salk Licenses or other applicable third party licenses. In respect of Licensed Compounds and Licensed Products in the Territory, Acceleron shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate to stop infringing activities in the Field in the Territory with respect to (including initiating or prosecuting an infringement or other appropriate suit or action against any Third Party who at any time has infringed, or is suspected of infringing, or defending any declaratory judgment action with respect to) any Acceleron Patent Rights claiming or relating to Licensed Compounds or Licensed Products (including Acceleron Patent Rights resulting from Acceleron Collaboration IP) or of using without proper authorization any Acceleron Know-How and Acceleron Improvements. In the event that Acceleron elects not to take action pursuant to this Section 8.3.2(a), Acceleron shall so notify Celgene promptly in writing of its intention in good time to enable Celgene to meet any deadlines by which an action must be taken to establish or preserve any enforcement rights, and Celgene shall have the right (to the extent Acceleron has the ability to grant Celgene such right with respect to the Salk Patent Rights or other applicable third party Patent Rights), but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer.
- (b) <u>Acceleron Collaboration IP; Joint Technology</u>. The following terms shall apply to all Joint Technology and all Acceleron Collaboration IP (excluding Acceleron Patent Rights resulting from Acceleron Collaboration IP). In respect of Licensed Compounds and Licensed Products in the Territory, Celgene shall have the first right, but not the obligation, to take any reasonable measures it deems

appropriate to stop infringing activities in the Field in the Territory with respect to (including initiating or prosecuting an infringement or other appropriate suit or action against any Third Party who at any time has infringed, or is suspected of infringing, or defending any declaratory judgment action with respect to) any Joint Patent Rights claiming or relating to Licensed Compounds or Licensed Products or of using without proper authorization any Joint Improvements, Joint Collaboration IP or Acceleron Collaboration IP (excluding Acceleron Patent Rights resulting from Acceleron Collaboration IP). In the event that Celgene elects not to take action pursuant to this Section 8.3.2(b), Celgene shall so notify Acceleron promptly in writing of its intention in good time to enable Acceleron to meet any deadlines by which an action must be taken to establish or preserve any enforcement rights, and Acceleron shall have the right, but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer. In any enforcement action involving Joint Technology, the Parties agree to be joined as parties to such enforcement action if necessary to enable the enforcement action.

- (c) <u>Celgene Technology</u>. The following terms shall apply to all Celgene Patent Rights, Celgene Improvements, Celgene Collaboration IP and Celgene Know How owned by Celgene and, with respect to other Celgene Technology, to the extent permitted by the applicable licenses. Celgene shall have the sole right, but not the obligation, to take any reasonable measures it deems appropriate to stop infringing activities in the Field in the Territory, including initiating or prosecuting an infringement or other appropriate suit or action against any Third Party who at any time has infringed, or is suspected of infringing, or defending any declaratory judgment action with respect to, any Celgene Patent Rights claiming or relating to Licensed Compounds or Licensed Products or of using without proper authorization any Celgene Know-How, Celgene Improvements or Celgene Collaboration IP.
- 8.3.2(a) or 8.3.2(b) above shall have the sole and exclusive right to select counsel for any such suit (which counsel shall be reasonably acceptable to the other Party) and shall pay all expenses of the suit, including attorneys' fees and court costs and reimbursement of the other Party's reasonable out-of-pocket expense in rendering assistance requested by the initiating Party. If required under Applicable Law in order for the initiating Party to initiate or maintain such suit, or if either Party is unable to initiate or prosecute such suit solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party shall join as a party to the suit and shall execute and cause its Affiliates to execute all documents necessary for the initiating Party to initiate litigation to prosecute and maintain such action. The initiating Party will keep the other Party reasonably informed of the status of the infringement suit. At the initiating Party's request, the other Party shall provide reasonable assistance to the initiating Party in connection with an infringement suit at no charge to the initiating Party except for reimbursement by the initiating Party of reasonable out-of-pocket expenses incurred in

rendering such assistance. The non-initiating Party may participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit under <u>Section 8.3.2(a)</u> or <u>8.3.2(b)</u>, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation), such amounts shall be allocated as follows:

- (a) to reimburse each Party for all expenses of the suit, including attorneys' fees and disbursements, court costs and other litigation expenses; and
- (b) any remaining amount shall be [\* \* \*].

#### 8.4 Claimed Infringement of Third Party Rights .

- 8.4.1. Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of their respective Affiliates or Sublicensees, claiming infringement of such Third Party's patent rights or unauthorized use or misappropriation of its know-how based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of a Licensed Compound or Licensed Product in the Territory ("Infringement Claim"), such Party shall promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served. Each Party agrees to make available to the other Party its advice and counsel regarding the technical merits of any such claim at no cost to the other Party and to offer reasonable assistance to the other Party at no cost to the other Party.
- 8.4.2. <u>Right to Defend</u>. Celgene shall have the right, but not the obligation, to defend any Infringement Claim brought against Celgene or its Affiliates or Sublicensees arising out of the Development, Manufacture or Commercialization of a Licensed Compound or Licensed Product in the Territory. With respect to any such Infringement Claim brought against Acceleron or its Affiliates, Acceleron shall notify Celgene, and the Parties, in good faith, shall determine who should defend such suit. All litigation costs and expenses incurred by the Defending Party (as defined below) in connection with such Infringement Claim, and all damages, payments and other amounts awarded against, or payable by, either Party under any settlement with such Third Party shall be borne by the Defending Party.
- 8.4.3. Procedure. The Party having the obligation or first right to defend an Infringement Claim shall be referred to as the "Defending Party." The Defending Party shall have the sole and exclusive right to select counsel for any Infringement Claim; provided that such counsel shall be reasonably acceptable to the other Party. The Defending Party shall keep the other Party fully informed of any such claims, shall consult with the other Party with respect to the strategy and conduct of any defense of such claims, and shall provide the other Party with copies of all documents filed in, and all written communications relating to, any suit brought in connection with such claims, which copies of documents filed or communications sent by the Defending Party will be provided in advance of filing or sending. The other Party may provide comments and suggestions with respect to any material actions to be taken by the Defending Party, and the Defending Party shall

reasonably consider all comments and suggestions and shall take all prosecution actions reasonably recommended by the other Party. The other Party may also participate and be represented in any such claim or related suit, at its own expense. The other Party shall have the sole and exclusive right to control the defense of an Infringement Claim in the event the Defending Party fails to exercise its right to assume such defense within thirty (30) days following written notice from the other Party of such Infringement Claim. No Party shall settle any claims or suits involving rights of another Party (or rights of such Party to the extent they are licensed to such other Party) without obtaining the prior written consent of such other Party, which consent shall not be unreasonably withheld.

- 8.4.4. <u>Limitations</u>. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN <u>SECTION 12.7</u>, THE FOREGOING STATES THE ENTIRE RESPONSIBILITY OF ACCELERON AND CELGENE, AND THE SOLE AND EXCLUSIVE REMEDY OF ACCELERON OR CELGENE, AS THE CASE MAY BE, IN THE CASE OF ANY CLAIMED INFRINGEMENT OF ANY THIRD PARTY PATENT RIGHTS OR UNAUTHORIZED USE OR MISAPPROPRIATION OF ANY THIRD PARTY'S KNOW-HOW.
- 8.5 **Other Infringement Resolutions**. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the types described in <u>Sections 8.3</u> and <u>8.4</u> of this Agreement ( *e.g.*, actions seeking declaratory judgments and revocation proceedings), the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute shall apply.
- 8.6 **Product Trademarks & Product Designation**. Celgene shall select and own the Product Trademarks for each Licensed Product and shall be solely responsible for filing and maintaining the Product Trademarks in the Territory. Celgene shall assume full responsibility, at its sole cost and expense, for any infringement of a Product Trademark for a Licensed Product by a Third Party (and shall retain in full any recoveries for such infringement) and shall defend and indemnify Acceleron for and against any claims of infringement of the rights of a Third Party by Acceleron's use of a Product Trademark in connection with a Licensed Product in accordance with the terms of this Agreement. In addition, Celgene shall have the right to select the product designation or generic name for the Licensed Compounds and Licensed Product, including changing the designation of ActRIIA and the fusion protein ACE-011.
- 8.7 **Marking**. Each Party agrees to mark, and to require any Affiliate or Sublicensee, to mark any Licensed Product (or their containers or labels) made, sold, or otherwise distributed by it or them with any notice of patent rights necessary or desirable under Applicable Law to enable the Acceleron Patent Rights to be enforced to their full extent in any country where Licensed Products are made, used, sold, or offered for sale. In all countries within North America, to the extent legally permissible, both Parties' names and logos will appear with equal prominence on Licensed Product labels and promotional materials. In any such country within North America where this is not legally permitted, the Parties agree to work together in good faith to identify a mechanism to allow the association of both Parties' names with the Product.
- 8.8 **Patent Term Extensions**. The Parties shall use reasonable efforts to obtain all available supplementary protection certificates ("SPC") and other extensions of the Acceleron Patent

Rights and Joint Patent Rights (including those available under the Hatch-Waxman Act). Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining patent term restorations, extensions or SPCs wherever applicable to Acceleron Patent Rights or Joint Patent Rights. The Party first eligible to seek patent term restoration or extension of any such Patent Rights or any SPC related thereto may do so; <u>provided</u> that, if in any country the first Party has an option to extend the patent term for only one of several patents, the first Party shall consult with the other Party before making the election. If more than one patent is eligible for extension or patent term restoration, the Parties shall select in good faith a strategy that shall maximize patent protection and commercial value for each Licensed Product. All filings for such extensions and certificates shall be made by the Party to whom responsibility for Prosecution of the Acceleron Patent Rights or Joint Patent Rights are assigned; <u>provided</u> that, in the event that the Party to whom such responsibility is assigned elects not to file for an extension or SPC, such Party shall (a) inform the other Party of its intention not to file, (b) grant the other Party the right to file for such extension or SPC in the Patent Rights' owner's name, and (c) provide all necessary assistance in connection therewith.

#### Article 9

#### **CONFIDENTIALITY**

### 9.1 **Confidential Information**.

- 9.1.1. Confidentiality. All Confidential Information disclosed by a Party to the other Party during the Agreement Term shall be used by the receiving Party solely in connection with the activities contemplated by this Agreement, shall be maintained in confidence by the receiving Party and shall not otherwise be disclosed by the receiving Party to any other person, firm, or agency, governmental or private (other than a Party's Affiliates), without the prior written consent of the disclosing Party. Acceleron and Celgene each agrees that it shall provide Confidential Information received from the other Party only to its employees, consultants and advisors, and to the employees, consultants and advisors of such Party's Affiliates or Sublicensees, and Third Parties acting on behalf of such Party, who have a need to know and have an obligation to treat such information and materials as confidential, which obligations are no less stringent than those contained in this <u>Article 9</u>. Each Party shall be responsible for a breach of this <u>Article 9</u> by its Affiliates, Sublicensee, Third Parties acting on behalf of such Party, and their respective employees, consultants and advisors. All obligations of confidentiality imposed under this <u>Article 9</u> shall expire [\* \* \*].
- 9.1.2. <u>Authorized Disclosure</u>. Notwithstanding the provisions of <u>Sections 9.1.1</u>, <u>9.2</u>, or <u>9.3</u>, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to:
  - (a) comply with Applicable Laws (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process;

- (b) Prosecute Patent Rights as contemplated by this Agreement;
- (c) defend or prosecute litigation in accordance with <u>Article 8</u>; <u>provided</u> that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure;
- (d) make filings and submissions to, or correspond or communicate with, any Regulatory Authority or clinical registry, including for purposes of obtaining authorizations to conduct Clinical Trials of, and to Commercialize, Licensed Products pursuant to this Agreement; and
- (e) exercise its rights hereunder (including, with respect to Celgene, disclosures to potential Sublicensees); <u>provided</u> such disclosure is covered by terms of confidentiality similar to those set forth herein.

In the event a Party shall deem it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this <u>Section 9.1.2</u>, such Party shall (i) to the extent possible give reasonable advance notice of such disclosure to the other Party sufficiently prior to making such disclosure so as to allow the other Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, (ii) provide reasonable assistance to the other Party with respect thereto, and (iii) take reasonable measures to ensure confidential treatment of such information.

- 9.1.3. Acceleron's Use of Confidential Information. Celgene acknowledges the fact that as a private company, Acceleron shall, from time to time, engage in fundraising activities with private investors. Acceleron may disclose this Agreement, including its terms and subject matter, under terms of confidentiality no less strict than those contained in this Agreement, to such investors or potential investors (including potential acquirers) in or potential licensees of Acceleron conducting due diligence in each instance. Acceleron shall provide Celgene with a list of all such persons executing such confidentiality agreements and shall be responsible for a breach of this Article 9 by such persons. Celgene shall permit a copy of this Agreement to be provided to Salk as a requirement of the Salk License, such copy to be considered confidential information under the Salk License and to be redacted to the extent permitted under the Salk License, which redaction shall be subject to the prior written approval of Celgene.
- 9.1.4. <u>ACE-536 Agreement</u>. The Parties acknowledge and agree that Confidential Information disclosed pursuant to this Agreement may have application to the Parties' rights and obligations under the ACE-536 Agreement and *vice versa*. Therefore, the Parties agree that information can be deemed Confidential Information under this Agreement and "Confidential Information" under the ACE-536 Agreement and that such information will be subject to the confidentiality and non-use obligations of both agreements.
- 9.1.5. <u>Joint Technology</u>. The Parties agree that, in order to effectuate the provisions of <u>Section 4.4.2</u>, subject to any exclusive licenses granted hereunder, (a) the non-use

provisions of this <u>Article 9</u> shall not apply to each Party's use of Joint Technology, and (b) each Party may disclose the Joint Technology to Third Parties who are under terms of confidentiality no less strict than those contained in this Agreement.

- **Publication Review**. Except as required by Applicable Law or, subject to the last sentence of this Section, as may be permitted under any agreement identified on Schedule 2.8, from and after the Effective Date, Celgene shall have the sole right to publish or present the results of any work relating to the Licensed Products or Licensed Compounds in the Field; provided that Acceleron shall have the right to publish or present works relating solely to Acceleron Development Activities (the Party entitled to publish pursuant to this Section being hereafter referred to as the "Publishing Party"). The Publishing Party shall publish or present such results (i) in a manner consistent with the publication strategy developed by either the Joint Development Committee or the Joint Commercialization Committee and (ii) after providing the other Party with the right to review such publications or presentations to ensure the other Party's Confidential Information is not included without the other Party's consent. In that respect, the Publishing Party shall provide to the other Party for review any (a) abstracts, posters and slide presentations prior to any scientific meetings, and such other Party shall have at least [\* \* \*] Business Days to provide feedback to such other Party, and (b) primary and final manuscripts and review articles prior to journal submission, and such other Party shall have at least [\* \* \*] Business Days to provide feedback. The Party that is not the Publishing Party may require that its Confidential Information that may be disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation. Acceleron's right to publish hereunder will be subject to the prior consent of Celgene, such consent not to be unreasonably withheld or delayed and which consent shall be deemed given if Celgene has not objected to any such publication within the applicable [\* \* \*] periods described above. If (x) a Third Party that is a party to an agreement identified on Schedule 2.8 is permitted to publish or present the results of any work conducted by such Third Party pursuant to such agreement and relating to the Licensed Products or Licensed Compounds in the Field, and (y) such Third Party is required to present such publication or presentation to Acceleron for prior review or approval, then (1) to the extent that Acceleron is permitted to disclose to Celgene such publications or presentations. Acceleron shall disclose such publications or presentations to Celgene, (2) to the extent that Acceleron is not permitted to disclose to Celgene such publications or presentations, Acceleron shall notify Celgene in the event such a publication or presentation has been submitted to Acceleron by such a Third Party, and (3) with respect to such publications or presentations (regardless of whether they were disclosed to Celgene or Celgene was merely notified of them), Acceleron shall take any action requested by Celgene, including withholding consent to such publication or presentation, to the extent Acceleron has the right to take such action under the applicable agreement with such Third Party.
- 9.3 **Public Announcements and Use of Names** . No disclosure of the existence of, or the terms of, this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, in each case, without the prior written permission of the other Party, except as may be required by law or expressly permitted by the terms hereof, including <u>Section 9.1.2</u>. A press release announcing this Agreement is attached

to this Agreement as Schedule 9.3, which may be released by either Party on the date agreed to by the Parties. Except for issuing such press release and subsequent announcements of the information contained in such press release, neither Party shall originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the execution of this Agreement, the subject matter of this Agreement or any activities contemplated hereby, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party, except as may be required by law or expressly permitted by the terms hereof, including Section 9.1.2. Notwithstanding the foregoing, Celgene, in its sole discretion, may determine the timing and content of any press release with respect to activities conducted hereunder beginning with the Phase 2B Clinical Trials with respect to each Licensed Compound or Licensed Product and all activities thereafter; provided that Celgene may not use Acceleron's name in any such press release without the prior written consent of Acceleron, except for the limited purpose of identifying Acceleron as the licensor of the Acceleron Technology and the party conducting the Phase 1 Clinical Trials and Phase 2A Clinical Trials or for purpose of republishing materials that have previously been published in accordance with this Section 9.3: provided further that Acceleron, to the extent required by applicable securities laws, may issue any press release with respect to activities conducted hereunder beginning with the Phase 2B Clinical Trials with respect to each Licensed Compound or Licensed Product so long as Acceleron provides Celgene with prior written notice, allows Celgene a reasonable opportunity to comment on the content of such disclosure, and consults with Celgene with respect to such comments. Notwithstanding the foregoing, once a public announcement is approved in accordance with this Section 9.3, a Party may reuse and subsequently disclose the information in such public announcement and may continue to disclose the contents of such public announcement without resubmitting such materials for further approval; provided that such Party does not materially change content and/or the manner in which the name, trademark, trade name or logo of the other Party is used.

#### Article 10

#### **EFFECTIVENESS**

- 10.1 **Effective Date** . Except for the Parties' obligations under this <u>Article 10</u> and the Parties representations and warranties (and disclaimers thereof) in <u>Article 12</u>, this Agreement shall not become effective until the Effective Date.
- 10.2 **Filings**. The Parties shall cooperate with one another in the preparation, execution and filing of all documents that are required (as reasonably determined by Celgene) to be filed pursuant to the HSR Act and will promptly file the same after the Execution Date. The related filing fees associated with the submission under the HSR Act shall be paid by Celgene.
- 10.3 **Closing** . As promptly as practicable after the Execution Date and after the satisfaction by each Party or, if permissible, waiver of the conditions set forth in Section 10.4, the Parties hereto shall cause the Closing to occur on the Effective Date. The Closing shall be held at the offices of Jones Day, 222 East 41st Street, New York, New York 10017, or such other place as the Parties shall agree, for the purpose of confirming the satisfaction or waiver, as the case may be, of the conditions set forth in Section 10.4. If the Effective Date has not occurred prior to May 31,

2008, either Party may terminate this Agreement upon written notice to the other Party; <u>provided</u>, <u>however</u>, that, as of such date, the Party terminating this Agreement is not in default under this Agreement.

- 10.4 **Conditions to Closing**. The obligation of each Party to close shall be subject to the satisfaction on or before the Effective Date of the following conditions any or all of which may be waived in whole or in part by such Party:
  - 10.4.1. the expiration or termination of all applicable waiting periods under the HSR Act, unless a joint determination is made by Celgene and Acceleron (by certification from Celgene and Acceleron to each other) that notification under the HSR Act is not required;
  - 10.4.2. the representations and warranties made by the other Party in <u>Article 12</u> shall be true and correct in all material respects as of the Effective Date with the same force and effect as if they had been made as of the Execution Date, and the other Party shall have performed all obligations and conditions herein required to be performed or observed by it on or prior to Closing; and
  - 10.4.3. the provision by each Party to the other Party of an officer's certificate certifying that <u>Section 10.4.1</u> and <u>10.4.2</u> above are true and correct with respect to such first Party as of the Effective Date.

#### Article 11

#### TERM AND TERMINATION

11.1 **Term**. The term of this Agreement shall commence on the Effective Date and expire, unless this Agreement is terminated earlier in accordance with this Article 11, on a country-by-country basis, upon the occurrence of both of the following: (a) the expiration of the Royalty Term with respect to all Licensed Products in such country in the Territory, and (b) Celgene has exercised or forfeited its option with regard to each Option Compound. For the avoidance of doubt, Section 11.1(a) shall be deemed to have occurred on the date on which no Development or Commercialization activities for any Licensed Compound or Licensed Product are ongoing and, according to the Joint Development Committee and Joint Commercialization Committee, no additional Development or Commercialization activities, respectively, are expected to commence. Upon the occurrence of the events described in clause (a) above, all licenses granted by Acceleron under this Agreement for such Licensed Product or Licensed Compound in such country shall become fully paid-up, perpetual, non-exclusive, sublicensable, irrevocable, royalty-free licenses.

#### 11.2 **Termination for Cause** .

11.2.1. <u>Cause for Termination</u>. This Agreement may be terminated at any time during the Agreement Term:

- (a) upon written notice by either Party if the other Party (the "Breaching Party") is in breach of its material obligations hereunder and has not cured such breach within [\* \* \*] (or [\* \* \*] for breaches of payment obligations) after notice requesting cure of the breach; provided that, notwithstanding the foregoing, in the event of a breach of a material obligation that is capable of being cured, but is not reasonably capable of being cured within the [\* \* \*] cure period, if the Breaching Party (i) proposes within such [\* \* \*] period a written plan to cure such breach within a defined time frame, and (ii) makes good faith efforts to cure such default and to implement such written cure plan, then the non-breaching Party may not terminate this Agreement for so long as the Breaching Party is diligently pursuing such cure in accordance with such plan; or
- (b) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the event of any involuntary bankruptcy or receivership proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within [\* \* \*] after the filing thereof. Celgene acknowledges that pursuant to the Salk License, Salk may terminate the Salk License immediately with no further notice obligation or opportunity to cure if Acceleron becomes insolvent, makes an assignment for the benefit of creditors, has a petition in bankruptcy filed for or against it or has a receiver or trustee in bankruptcy or similar officer appointed to take charge of all or part of Acceleron's property; provided that the provisions of Section 4.5.4 hereof would apply.

#### 11.2.2. Effect of Termination for Cause.

- (a) <u>Termination by Acceleron</u>. Without limiting any other legal or equitable remedies that Acceleron may have, if Acceleron terminates this Agreement in accordance with <u>Section 11.2.1</u>, then, except for the licenses granted in <u>Section 11.5</u>, all licenses granted under this Agreement shall terminate.
- (b) <u>Termination by Celgene</u>. Without limiting any other legal or equitable remedies that Celgene may have, if Celgene terminates this Agreement in accordance with <u>Section 11.2.1</u>, then the license granted to Acceleron pursuant to <u>Section 4.2</u> shall terminate, the licenses granted to Celgene under <u>Section 4.1</u> shall continue in perpetuity and (i) all future royalties payable by Celgene under this Agreement shall be reduced by [\* \* \*] percent [\* \* \*]; (ii) Celgene shall have no obligation to pay any milestones arising under this Agreement after the date of such termination; (iii) Acceleron's obligations under <u>Article 6</u> (Exclusivity) shall survive such termination for as long as Celgene is paying royalties pursuant hereto; and (iv) Acceleron shall continue to be solely responsible for all royalty, milestone, and other payments owed to Salk or any other third party licensor pursuant to an agreement executed by Acceleron prior to the Effective Date (or,

with respect to any Option Compound, prior to the date that such Option Compound is deemed a Licensed Compound in accordance with <a href="Article 7">Article 7</a>); provided that, if Acceleron is the Breaching Party and Celgene terminates this Agreement in accordance with <a href="Section 11.2.1(a)">Section 11.2.1(a)</a> for a breach by Acceleron of its material obligations under <a href="Article 6">Article 6</a> (Exclusivity) or if Acceleron breaches such <a href="Article 6">Article 6</a> (Exclusivity) following termination during the period such obligations survive as provided in this <a href="Section 11.2.1(b)">Section 11.2.1(b)</a>, then Celgene shall have no further obligation to pay any royalties hereunder based on Net Sales arising after the date of such termination, but Celgene shall be responsible for paying any royalties due to Salk and other Third Parties pursuant to <a href="Section 5.6.3(c)">Section 5.6.3(c)</a> with respect to activities of Celgene in exercising such licenses.

- 11.3 **Termination for Convenience** . At any time, Celgene may terminate this Agreement, on a country-by-country or Licensed Product-by-Licensed Product basis or in its entirety, for any reason, upon one hundred eighty (180) days' advance written notice to Acceleron.
- 11.4 **Termination for Failure to Meet End Points** . If a Licensed Compound or Licensed Product fails to meet the end point criteria set by the Joint Development Committee pursuant to <u>Section 3.3</u> for a particular Clinical Trial or Development activity, Celgene may terminate this Agreement, on a Licensed Product-by-Licensed Product basis or in its entirety, upon 45 days' advance written notice to Acceleron.
- 11.5 **Other Effects of Termination**. In the event that Acceleron terminates this Agreement for cause under <u>Section 11.2.1</u> or Celgene terminates this Agreement for convenience under Section 11.3 or for failure to meet end points under Section 11.4:
  - 11.5.1. <u>License and Assignment</u>. All licenses granted to Celgene under this Agreement with respect to the applicable country or Licensed Product shall terminate. Celgene (a) hereby grants (effective only upon any such termination of this Agreement) to Acceleron a worldwide, non-exclusive, non-transferable license, with the right to sublicense (under the same terms that Celgene may sublicense its rights pursuant to <u>Section 4.3</u>), under the Celgene Technology to offer for sale, sell, make, have made, use and import Licensed Compounds (and Option Compounds to the extent that they have become Licensed Compounds at the time of termination pursuant to <u>Section 7.2</u>) and Licensed Products in the Field in the Territory, which license shall be (i) royalty-free in the event that Celgene terminates this Agreement for convenience under <u>Section 11.3</u> or for failure to meet clinical endpoints under <u>Section 11.4</u> or Acceleron terminates this Agreement for cause under <u>Section 11.2.1</u> for a breach by Celgene of its material obligations under <u>Article 6</u> (Exclusivity), and (ii) royalty-bearing in the event that Acceleron terminates this Agreement for any other cause under <u>Section 11.2.1</u>, with the royalties to be paid by Acceleron to Celgene equal to [\* \* \*] percent [\* \* \*] of the royalties payable by Celgene to Acceleron under this Agreement; (b) shall assign or sublicense to Acceleron, to the extent possible and as requested by Acceleron, Celgene's rights and obligations under any Third Party licenses entered into pursuant to <u>Sections 5.6.3(b)</u> or <u>5.6.3(c)</u>, (c) shall assign to Acceleron all of its rights, title and interest in Product Trademarks, and (d) shall transfer to

Acceleron ownership of any NDAs or Regulatory Approvals then in Celgene's name related to Licensed Compounds or Licensed Products and notify the appropriate Regulatory Authorities and take any other action reasonably necessary to effect such transfer of ownership. If ownership of an NDA or Regulatory Approval cannot be transferred to Acceleron in any country, Celgene hereby grants (effective only upon any such termination of this Agreement) to Acceleron a permanent, exclusive (even as to Celgene) and irrevocable right of access and reference to such NDAs and Regulatory Approvals for Licensed Compounds and Licensed Products in such country in the Field. The royalties to be paid by Acceleron to Celgene shall be paid under the terms specified in Sections 5.6 and 5.7, in each case substituting "Acceleron" for "Celgene" and vice versa with respect to all obligations and definitions, and otherwise *mutantis mutandis*.

- 11.5.2. <u>Transfer of Materials</u>. In the event Acceleron exercises its rights pursuant to <u>Section 11.5.1</u>, Celgene shall negotiate in good faith with Acceleron regarding Celgene transferring to Acceleron, at Acceleron's cost, materials developed under this Agreement in the course of Developing and Commercializing Licensed Compounds or Licensed Products that are directly related to Licensed Compounds or Licensed Products to the extent provided in and in accordance with such agreement.
- 11.5.3. <u>Confidential Information</u>. Notwithstanding <u>Section 9.1.1</u>, which provides that obligations of confidentiality shall expire [\* \* \*] years following termination or expiration of this Agreement, for so long as the Celgene Know-How, Celgene Improvements or Celgene Collaboration IP to be licensed to Acceleron pursuant to <u>Section 11.5.1</u> remain Confidential Information, Acceleron's obligations of confidentiality pursuant to Article 9 shall survive and continue in full force and effect.
- 11.5.4. Continuity of Supply. Except in the event of a termination of this Agreement pursuant to Section 11.4, in the event that Celgene has begun Manufacture of Clinical Supplies or Commercial Supplies pursuant to Section 2.4, then at Acceleron's request, Celgene shall continue to Manufacture and supply Acceleron with such Clinical Supplies or such Commercial Supplies, as applicable, at [\* \* \*], for an additional [\* \* \*] after termination for Clinical Supplies and for an additional [\* \* \*] after termination for Commercial Supplies; provided, however, that Celgene shall not be obligated to Manufacture or supply such Clinical Supplies or Commercial Supplies in excess of the greater of (i) the anticipated amounts of such supply as set forth in the applicable Development Plan/Budget or Commercialization Plan/Budget for such [\* \* \*] or (ii) the amount of such Clinical Supplies or Commercial Supplies Manufactured by Celgene in the [\* \* \*] prior to termination. In the event that the Clinical Supplies or Commercial Supplies are being Manufactured by a Third Party under contract, to the extent permitted by the terms of such contract, Celgene shall assign such contracts to Acceleron. For all future Third Party Manufacturing contracts related to the Licensed Compounds or Licensed Products, Celgene shall use Commercially Reasonable Efforts to ensure that such contracts are assignable to Acceleron in the event of termination of this Agreement as provided in Section 11.5.1.

- 11.6 **Sell-Down** . If Celgene, its Affiliates or Sublicensees at termination of this Agreement possess Licensed Product, have started the Manufacture thereof or have accepted orders therefor, Celgene, its Affiliates or Sublicensees shall have the right, for up to [\* \* \*] following the date of termination, to sell their inventories thereof, complete the Manufacture thereof and Commercialize such fully-Manufactured Licensed Product, in order to fulfill such accepted orders or distribute such fully-Manufactured Licensed Product, subject to the obligation of Celgene to pay Acceleron the royalty payments as provided in <u>Article 5</u> of this Agreement.
- 11.7 **Transfer of Records** . Upon expiration of this Agreement or in the event that Celgene terminates this Agreement for cause under <u>Section 11.2.1</u>, Acceleron will continue to maintain all records described in <u>Section 2.2</u> or transfer them to Celgene, as requested by Celgene.
- 11.8 **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by Acceleron or Celgene, including <u>Article 4</u>, are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "**IP**"). The Parties agree that Celgene or Acceleron, as applicable, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. Upon the bankruptcy of Acceleron or Celgene, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such IP, and such IP, if not already in such Party's possession, shall be promptly delivered to such Party.
- 11.9 **Effect of Expiration or Termination; Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of <u>Article 9</u>, <u>Article 11</u>, <u>Article 12</u>, <u>Article 13</u> and <u>Sections 4.3.3</u>, <u>4.4</u>, <u>4.5.4</u>, <u>12.5</u>, <u>12.6</u>, <u>12.7</u>, as well as <u>Sections 8.2</u>, <u>8.3</u>, <u>8.4.4</u> and <u>8.6</u> (but only to the extent that Celgene's exclusive license survives pursuant to <u>Section 11.2.2(b)</u>) shall survive any expiration or termination of this Agreement. Except as set forth in this <u>Article 11</u>, upon termination or expiration of this Agreement all other rights and obligations cease. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

### Article 12

#### REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

- 12.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that as of the Execution Date and as of the Effective Date of this Agreement:
  - 12.1.1. It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof. Further, except for any Regulatory Approvals, pricing or reimbursement approvals, manufacturing approvals or similar

approvals necessary for the Development, Manufacture or Commercialization of the Licensed Compounds and Licensed Products, and except for any approvals under the HSR Act, all necessary consents, approvals and authorizations of all government authorities required to be obtained by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Effective Date.

#### 12.1.2.

It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

12.1.3. This Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound.

#### 12.2

**Acceleron Representations and Warranties** . Acceleron represents and warrants to Celgene that as of the Execution Date and as of the Effective Date of this Agreement:

- 12.2.1. Acceleron Controls the Acceleron Patent Rights existing as of the Effective Date and is entitled to grant the licenses specified herein. The Acceleron Patent Rights existing as of the Effective Date constitute all of the Patent Rights Controlled by Acceleron as of the Effective Date that relate to or are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field. Acceleron has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Acceleron Technology in a manner that conflicts with any rights granted to Celgene hereunder. During the Agreement Term, Acceleron shall not encumber the rights granted to Celgene hereunder with respect to the Acceleron Patent Rights.
- 12.2.2. Acceleron Controls the Option Patent Rights existing as of the Effective Date and is entitled to grant the options for licenses specified herein. During the Agreement Term, Acceleron shall not encumber the Option Patent Rights in a manner that conflicts with any rights granted to Celgene hereunder.
- 12.2.3. To the best knowledge of Acceleron and its Affiliates, there is no actual or threatened infringement of the Acceleron Patent Rights or the Option Patent Rights in the Field by any Third Party or any other infringement or threatened infringement that would adversely affect Celgene's rights under this Agreement.
- 12.2.4. There are no claims, judgments or settlements against or owed by Acceleron or its Affiliates or pending or, to the best knowledge of Acceleron and its Affiliates, threatened claims or litigation relating to the Acceleron Technology that would impact activities under this Agreement.

- 12.2.5. The Salk License, as set forth in Exhibit A, is in full force and effect and has not been modified or amended.
- 12.2.6. Neither Acceleron nor, to the best knowledge of Acceleron, Salk is in default with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the Salk License.
- 12.2.7. To the best knowledge of Acceleron, the Salk Patent Rights were not and are not subject to any restrictions or limitations except as set forth in the Salk License, a true and correct copy of which is attached as Exhibit A.
- 12.2.8. Acceleron has not waived or allowed to lapse any of its rights under the Salk License with respect to Licensed Compounds or Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.
- 12.2.9. As of the Effective Date, neither Acceleron nor any of its respective employees or, to the best knowledge of Acceleron or its Affiliates, its agents, in their capacity as such, have been disqualified or debarred by the FDA, pursuant to 21 U.S.C. §§ 335(a) or (b), or been charged with or convicted under United States law for conduct relating to the development or approval, or otherwise relating to the regulation of any Licensed Product under the Generic Drug Enforcement Act of 1992, or any other relevant law, rule, or regulation or been disbarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.
- 12.2.10. ActRIIA is a "Primary Licensed Product" under the Salk License, and, if ActRIIA becomes a "Secondary Licensed Product" under the Salk License, Acceleron will continue to have the right to grant to Celgene a sublicense of all of Acceleron's rights under the Salk License to the extent set forth in this Agreement without any alteration from the granted rights associated with a "Primary Licensed Product," except that the license from Salk becomes non-exclusive.
- 12.2.11. The Acceleron Patent Rights, and to the best knowledge of Acceleron or its Affiliates, the Salk Patent Rights, have been filed and diligently prosecuted in accordance with all Applicable Laws in the Territory and have been maintained, with all applicable fees with respect thereto having been paid.
- 12.2.12. To the best knowledge of Acceleron or its Affiliates, each of the issued Acceleron Patents Rights is valid and enforceable.
- 12.2.13. To the best knowledge of Acceleron (after due investigation), there have been no patent applications arising from research funded by [\* \* \*] since the effective date of [\* \* \*], as described in [\* \* \*] except for U.S. patent application Nos. [\* \* \*] and [\* \* \*] and all foreign counterparts thereto and all provisional applications, continuations, continuations-in-part, and divisions thereof.

- 12.2.14. For purposes of exercising its rights or performing its obligations hereunder in Developing, Manufacturing and Commercializing Licensed Compounds or Licensed Product [\* \* \*], Celgene does not need access or a license to (a) the patent rights specified in Section 12.2.13 or (b) to the best knowledge of Acceleron or its Affiliates, any and all Know-How, Patent Rights, or other intellectual property rights that are licensed to Acceleron or its Affiliates or that they otherwise have access to but are not Controlled by Acceleron or its Affiliates pursuant hereto.
- 12.3 **Option Compound Representations and Warranties**. Immediately prior to an Option Compound becoming a "Licensed Compound" pursuant to <u>Article 7</u>, Acceleron shall represent and warrant to Celgene the matters set forth in <u>Section 12.2</u> with respect to such Option Compound or shall notify Celgene of which representations and warranties, if any, are untrue.
- 12.4 **Celgene Representations and Warranties**. Celgene represents and warrants to Acceleron that as of the Execution Date and as of the Effective Date of this Agreement, and to the best knowledge of Celgene or its Affiliates, there are no claims, judgments or settlements against or owed by Celgene or its Affiliates or pending or threatened claims or litigation relating to the Celgene Technology that would impact activities under this Agreement.
- 12.5 Warranty Disclaimer . EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED COMPOUND, OPTION COMPOUND OR LICENSED PRODUCT UNDER THIS AGREEMENT SHALL BE SUCCESSFUL.
- 12.6 **No Consequential Damages** . NEITHER PARTY HERETO SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS <u>SECTION 12.6</u> IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY'S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING [\*\*\*].

#### 12.7 Indemnification and Insurance.

12.7.1. <u>Indemnification by Celgene</u>. Celgene shall indemnify, hold harmless, and defend Acceleron, its Affiliates, and their respective directors, officers, employees and agents and

their respective successors, heirs and assigns ("Acceleron Indemnitees") from and against any and all Third Party claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorneys' fees and expenses of litigation) (collectively, "Losses") to the extent arising out of or resulting from (a) any breach of, or inaccuracy in, any representation or warranty made by Celgene in this Agreement, or any breach or violation of any covenant or agreement of Celgene in or pursuant to this Agreement; (b) the negligence or willful misconduct by or of Celgene, its Affiliates or Sublicensees, and their respective directors, officers, employees and agents; and (c) any product liability claims (under any theory, including actions in the form of tort, warranty or strict liability) relating to Celgene's Development, Manufacturing, and Commercialization activities under this Agreement. Celgene shall have no obligation to indemnify the Acceleron Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by Acceleron in this Agreement, or any breach or violation of any covenant or agreement of Acceleron in or pursuant to this Agreement, or the negligence or willful misconduct by or of any of the Acceleron Indemnitees.

- 12.7.2. <u>Indemnification by Acceleron</u>. Acceleron shall indemnify, hold harmless, and defend Celgene, its Affiliates, and their respective directors, officers, employees and agents and their respective successors, heirs and assigns ("Celgene Indemnitees") from and against any and all Losses to the extent arising out of or resulting from (a) any breach of, or inaccuracy in, any representation or warranty made by Acceleron in this Agreement, or any breach or violation of any covenant or agreement of Acceleron in or pursuant to this Agreement; (b) the negligence or willful misconduct by or of Acceleron, its Affiliates and their respective Sublicensees, and their respective directors, officers, employees and agents; or (c) any product liability claims (under any theory, including actions in the form of tort, warranty or strict liability) relating to Acceleron's Development, Manufacturing, and Commercialization activities under this Agreement. Acceleron shall have no obligation to indemnify the Celgene Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by Celgene in this Agreement, or any breach or violation of any covenant or agreement of Celgene in or pursuant to this Agreement, or the negligence or willful misconduct by or of any of the Celgene Indemnitees.
- 12.7.3. <u>Indemnification Procedure</u>. In the event of any such claim against any Celgene Indemnitee or Acceleron Indemnitee (individually, an "<u>Indemnitee</u>"), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee shall cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party shall not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party's prior written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in <u>Section 12.7.1</u> or <u>12.7.2</u> may apply, the indemnifying Party shall promptly notify the Indemnitees, which may be represented in any

such action or proceeding by separate counsel at their expense; <u>provided</u> that the indemnifying Party shall be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. Any other provision of this <u>Article 12</u> to the contrary, no Indemnitee under this Agreement shall be required to waive a conflict of interest under any applicable rules of professional ethics or responsibility if such waiver would be required for a single law firm to defend both the indemnifying Party and one or more Indemnitees. In such case, the indemnifying Party shall provide a defense of the affected Indemnitees through a separate law firm reasonably acceptable to the affected Indemnitees at the indemnifying Party's expense.

- 12.7.4. <u>Joint Defendants</u>. If a product liability suit is brought against either Party relating in any way to a Licensed Product or Licensed Compound, and it is not clear from the allegations in the complaint or the known facts surrounding the allegations in the complaint as to whether a claim exists for which there is a right of indemnification pursuant to <u>Section 12.7.1</u> or <u>12.7.2</u> above, then Celgene shall be responsible for controlling the defense of such suit in the first instance. During such period that Celgene is controlling such defense, with regard to the costs of such defense, including attorneys' fees, Celgene and Acceleron each shall be responsible for [\* \* \*] of all such costs. No settlement, consent judgment or other voluntary final disposition of any such suit may be entered into without the prior written consent of Acceleron, which consent shall not be unreasonably withheld or delayed. If, at any time in the course of such suit, it becomes apparent from discovery or otherwise that a claim exists for which indemnification may be obtained in accordance with <u>Section 12.7.1</u> or <u>12.7.2</u> above, then the indemnification provisions of either <u>Section 12.7.1</u> or <u>12.7.2</u> above, whichever is applicable, and the indemnification procedures of <u>Section 12.7.3</u> shall become applicable and govern further proceedings in the suit.
- 12.7.5. <u>Insurance</u>. As of the Effective Date and throughout the term of this Agreement, each Party shall procure and maintain, at its sole cost and expense, commercial general liability insurance and products liability coverage (each including broad form contractual liability coverage for such Party's indemnification obligation under <u>Section 12.7.1</u> or <u>12.7.2</u> above, as applicable) in amounts not less than [\* \* \*] per incident and [\* \* \*] annual aggregate; <u>provided</u> that after approval of the first NDA by a Regulatory Authority for use of a Licensed Product, such products liability coverage shall be increased to not less than [\* \* \*] per incident and [\* \* \*] annual aggregate. Each Party shall name the other Party as additional insureds on each such insurance policy relating to this Agreement. Celgene may elect to self-insure all or parts of the limits described above. The minimum amounts of insurance coverage required under this <u>Section 12.7.5</u> shall not be construed to create a limit of either Party's liability with respect to its indemnification obligation under <u>Section 12.7.1</u> or <u>12.7.2</u> above, as applicable.

Article 13

MISCELLANEOUS PROVISIONS

#### 13.1 Dispute Resolution; Governing Law.

- 13.1.1. <u>Disputes</u>. Unless otherwise set forth in this Agreement, in the event of any dispute arising under this Agreement between the Parties, the Parties may refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable resolve a given dispute pursuant to this <u>Section 13.1.1</u> within [\* \* \*] days of referring such dispute to the Executive Officers, either Party shall be free to pursue any remedy that may be available to it at law or in equity.
- 13.1.2. <u>Jurisdiction</u>. Each Party hereby (a) irrevocably submits to the exclusive jurisdiction of the United States District Court located in the State of New York and (b) agrees not to assert as a defense or otherwise that its property is exempt or immune from attachment or execution, that any such action brought in the above-named court should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than the above-named court, or should be stayed by reason of the pendency of some other proceeding in any other court other than the above-named court, or that this Agreement or the subject matter hereof may not be enforced in or by such court.
- 13.1.3. <u>Governing Law</u>. This Agreement shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding the provisions governing conflict of laws under such New York law to the contrary.
- Assignment . Except as provided in this <u>Section 13.2</u>, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party. Either Party may, however, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or pursuant to a Change of Control. To the extent that the assigning Party survives as a legal entity, the assigning Party shall remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned to such assignee.
- 13.3 **Amendments**. This Agreement and the Schedules referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.
- Notices . Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing and (a) delivered by hand, (b) sent by nationally recognized overnight delivery service, (c) sent by registered or certified mail, return receipt requested, postage prepaid, or (d) sent by facsimile transmission confirmed by prepaid, registered or certified mail letter, and shall be deemed to have been properly served to the addressee upon receipt of such written communication, in any event to the following addresses:

If to Acceleron: Acceleron Pharma, Inc.

149 Sidney Street Cambridge, MA 02139

Attn: President

Telephone: (617) 649-9200

Fax: (617) 576-2224

with a copy to: Ropes & Gray LLP

One International Place Boston, MA 02110

Attn: Marc A. Rubenstein Telephone: (617) 951-7000

Fax: (617) 235-0706

If to Celgene: [\* \* \*]

with a copy to:

Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided.

- 13.5 **Force Majeure** . No failure or omission by either Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the reasonable control of such Party, including the following: acts of god; acts or omissions of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; terrorist act; rebellion; insurrection; riot; and invasion; <u>provided</u> that such Party provides notice to the other Party of such an event, and the non-performing Party uses Commercially Reasonable Efforts to cure such failure or omission resulting from one of the above causes as soon as is practicable; <u>provided further</u> that, in the event the suspension of performance continues for [\* \* ] days, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the Parties will discuss how to proceed under this Agreement, which may include termination of this Agreement by the non-affected Party.
- 13.6 **Compliance with Applicable Laws**. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with United States export laws and regulations. The Parties shall at all times comply with all material laws and regulations applicable to its activities under this Agreement.
- 13.7 **Independent Contractors** . It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Acceleron or Celgene to act as agent for the other. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one Party

for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

- 13.8 **Further Assurances**. Each Party hereto agrees to execute, acknowledge and deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 13.9 **No Strict Construction**. This Agreement has been prepared jointly and shall not be strictly construed against either Party.
- 13.10 **Headings**. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.
- 13.11 **No Implied Waivers; Rights Cumulative**. No failure on the part of Acceleron or Celgene to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
- 13.12 **Severability**. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.
- 13.13 **No Third Party Beneficiaries** . No person or entity other than Celgene, Acceleron and their respective Affiliates and permitted assignees hereunder shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- 13.14 **Execution in Counterparts**. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

<u>Incorporation</u>. Article 13 of the Original Agreement is hereby incorporated *mutatis mutandis* into this Amendment.

<u>Effect on Original Agreement</u>. Except as specifically amended by this Amendment, the Original Agreement will remain in full force and effect and is hereby ratified and confirmed. To the extent a conflict arises between the terms of the Original Agreement and this Amendment, the terms of this Amendment shall prevail but only to the extent necessary to accomplish their intended purpose.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Collaboration, License and Option Agreement as of the date first set forth above.

ACCELERON PHARMA, INC.

By: <u>/s/ John Knopf</u> Name: <u>John Knopf</u>

Title: CEO

CELGENE CORPORATION

By: <u>/s/ Sol Barer</u> Name: <u>Sol Barer</u>

Title: Chairman and CEO

[Signature Page to Collaboration License and Option Agreement]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT
REQUEST. REDACTED MATERIAL IS MARKED WITH [* * *] AND HAS BEEN FILED SEPARATELY WITH THE
SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A
[A COPY OF THE SALK LICENSE]

#### **EXHIBIT B**

#### TERMS OF CLINICAL SUPPLY

Firm Orders: [\* \* \*]

Quantities of Clinical Supplies: [\* \* \*]

Delivery of Clinical Supplies: [\* \* \*]

Adjustments: [\* \* \*]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. WHERE TWO PAGES OF MATERIAL HAVE BEEN OMITTED, THE REDACTED MATERIAL IS MARKED WITH [†].

#### SCHEDULE 1.4 ACCELERON PATENT RIGHTS

Acceleron Dkt. No.	Title	Serial No.	Publication No.	Status	Filing Date
[†]	[†]	[†]	[†]	[†]	[†]

#### SCHEDULE 1.11 ACTIVIN A/ACTIVIN A ANTIBODY PATENT RIGHTS

Acceleron Dkt. No.	Title	Serial No.	Publication No.	Status	Filing Date
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]

#### SCHEDULE 1.14 ACTIVIN B/ACTIVIN B ANTIBODY PATENT RIGHTS

Acceleron Dkt. No.	Title	Serial No.	Publication No.	Status	Filing Date
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]

#### SCHEDULE 1.21 BMP-3/BMP-3 ANTIBODY PATENT RIGHTS

Acceleron Dkt. No.	Title	Serial No.	Publication No.	Status	Filing Date
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. WHERE TWO PAGES OF MATERIAL HAVE BEEN OMITTED, THE REDACTED MATERIAL IS MARKED WITH [†].

### SCHEDULE 2.8 THIRD PARTY SERVICE PROVIDERS

#### SCHEDULE 4.4.6 OUTSIDE COUNSEL FOR INVENTORSHIP/PATENT DISPUTES

[\* \* \*]

### SCHEDULE 6.2.3 DESIGNATED THIRD PARTY ACQUIRORS

[\* \* \*]

#### SCHEDULE 8.1 SALK PATENT RIGHTS

Attorney Docket No.	Title	Serial No.	Patent No.	Status	Filing Date	Issue Date
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]

#### SCHEDULE 9.3 PRESS RELEASE





#### Acceleron Pharma Announces Global Collaboration with Celgene Corporation on ACE-011 Program for Cancer-Related Bone Loss

CAMBRIDGE, Mass. & SUMMIT, N.J.— Feb. 20, 2008 - Acceleron Pharma, Inc. and Celgene Corporation today announced a worldwide strategic collaboration for the joint development and commercialization of ACE-011, a first-in-class, novel bone-forming compound. The collaboration combines both companies' resources and commitment to developing products for the treatment of cancer and cancer-related bone loss. In preclinical and early clinical studies, this innovative compound has reported success in key biomarkers of bone formation. The companies also signed an option agreement for certain discovery stage programs.

Under the terms of the agreement, Celgene and Acceleron will jointly develop, manufacture and commercialize Acceleron's products for bone loss. Celgene will make an upfront payment to Acceleron of \$50 million, which includes a \$5 million equity investment in Acceleron. In addition, in the event of an initial public offering of Acceleron, Celgene will purchase a minimum of \$7 million of Acceleron common stock.

"This collaboration is an excellent strategic fit for Acceleron and the ACE-011 program. Celgene is one of the most successful biotech companies in the world and is the leader in the field of blood cancers, including multiple myeloma, an indication where ACE-011 has great potential," said John Knopf, Ph.D., Chief Executive Officer of Acceleron. "We believe Celgene's established commercial, clinical, regulatory and international capabilities complemented by Acceleron's expertise in novel biologics drug discovery, manufacturing and development may result in a successful partnership that reflects a shared vision to improve the lives of patients worldwide."

Acceleron will retain responsibility for initial activities, including research and development, through the end of Phase 2a clinical trials, as well as manufacturing the clinical supplies for these studies. In turn, Celgene will conduct the Phase 2b and Phase 3 clinical studies and will oversee the manufacture of Phase 3 and commercial supplies. Acceleron will pay a share of the development expenses and is eligible to receive development, regulatory and commercial milestones of up to \$510 million for the ACE-011 program and up to an additional \$437 million for each of the three discovery stage programs. The companies will co-promote the products in North America. Acceleron will receive tiered royalties on worldwide net sales.

"Celgene supports the development of promising new approaches for the treatment of cancer and bone loss like ACE-011," said Sol Barer, Ph.D., Chairman and Chief Executive Officer of Celgene. "We look forward to the initiation of the ACE-011 Phase 2a study in multiple myeloma later this year."

The completion of the agreement is subject to Hart-Scott-Rodino approval under United States antitrust laws.

#### **About ACE-011**

ACE-011, a protein therapeutic based on the activin receptor type IIA, is a novel bone-forming agent. In numerous pre-clinical models of bone loss, ACE-011 increased bone mineral density, improved bone architecture, increased the mineral apposition and bone formation rates and improved bone mechanical strength. These effects have been demonstrated in therapeutic models of bone loss in which ACE-011 stimulated bone formation – a significant unmet medical need that is underserved by current treatments for bone loss. In its Phase 1 study, ACE-011 demonstrated an encouraging safety profile and increased biomarkers of bone formation. ACE-011 is currently in a Phase 1b study and Acceleron expects to begin a Phase 2a study in multiple myeloma in the middle of 2008.

#### **About Acceleron**

Acceleron is a privately held biopharmaceutical company committed to discover, develop, manufacture and commercialize novel biotherapeutics that modulate the growth of bone, muscle, fat and the vasculature to treat musculoskeletal, metabolic and cancer-related diseases. Acceleron's scientific approach takes advantage of its unique insight into the regenerative powers of two protein families: the Growth and Differentiation Factors (GDFs) and Bone Morphogenetic Proteins (BMPs). ACE-011, a novel bone forming agent, is the Company's lead program, and is being developed to reverse bone loss in diseases such as cancer-related bone loss. In addition, the company is advancing through pre-clinical development product candidates that increase muscle mass, control angiogenesis and inhibit fat accumulation. Acceleron utilizes proven biotherapeutic technologies and capitalizes on the company's internal GMP manufacturing capability to rapidly and efficiently advance its therapeutic programs. The investors in Acceleron are Advanced Technology Ventures, Bessemer Ventures, Flagship Ventures, MPM BioEquities, OrbiMed Advisors, Polaris Ventures, QVT Financial, Sutter Hill Ventures and Venrock. For more information, visit www.acceleronpharma.com.

#### **About Celgene**

Celgene Corporation, headquartered in Summit, New Jersey is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. For more information, please visit the Company's website at www.celgene.com.

This release contains forward-looking statements which are subject to known and unknown risks, delays, uncertainties and other factors not under Celgene's control, which may cause actual results, performance or achievements of Celgene to be materially different from the results, performance or other expectations expressed or implied by these forward-looking statements. These factors include results of current or pending research and development activities, actions by the FDA and other regulatory authorities, and other factors described in Celgene's filings with the Securities and Exchange Commission such as its 10K, 10Q and 8K reports.

#### CONTACT:

Celgene Corporation: Acceleron Pharma:

David Gryska, 908-673-9059 Steven Ertel, 617-649-9234

Senior Vice President and Chief Financial Officer Vice President, Corporate Development

or o

Brian P. Gill, 908-673-9530 Paul Kidwell (Media)

Vice President, Global Corporate Communications Suda Communications LLC, tel: 617-296-3854

# EXCLUSIVE LICENSE AGREEMENT BETWEEN ACCELERON PHARMA, INC. AND BETH ISRAEL DEACONESS MEDICAL CENTER

This License Agreement ("Agreement") is made as of the date immediately above the signatures of the Parties below ("Effective Date") between Beth Israel Deaconess Medical Center, a not-for-profit Massachusetts corporation, with a principal place of operation at 330 Brookline Avenue, Boston, Massachusetts 02215 ("BIDMC"), and Acceleron Pharma, Inc., a for-profit corporation, having a principal place of business at 128 Sidney Street, Cambridge, MA 02139 ("Licensee"), each referred to individually as a "Party" and collectively as the "Parties".

#### **RECITALS**

WHEREAS, BIDMC, as a center for patient care, research and education, owns certain Patent Rights (defined below) through assignment and desires to benefit the public by disseminating the results of its research through the grant of a license of those Patent Rights to Licensee for the commercial development, manufacture, distribution and use of Patented Products (defined below); and

WHEREAS, Licensee has the capability to commercially develop, manufacture, distribute and use Patented Products for public use and benefit and desires to receive a license to such Patent Rights; and

WHEREAS, Licensee enjoys certain rights under the terms and provisions of the Material Transfer Agreement between the Parties effective September 27, 2010 ("MTA");

NOW THEREFORE, for good and valuable consideration, the sufficiency of which the Parties acknowledge, the Parties agree as follows:

#### 1. DEFINITIONS

The following terms have the following meanings:

- 1.1 "<u>ALK1 Product</u>" means: (i) an ALK1 (activin receptor-like kinase 1) polypeptide comprising a ligand binding portion of the extracellular domain of a vertebrate ALK1, particularly human ALK1 (e.g. a fusion protein including the ALK1 ligand binding domain fused to an Fc portion of an IgG); (ii) an antibody that binds to the extracellular domain of human ALK1; (iii) an antibody that binds to human BMP9; or (iv) an antibody that binds to human BMP10. For clarity, proteins that include the amino acid sequence described as SEQ ID NO: 3 or SEQ ID NO:5 in U.S. Patent No. 8,158,584 are included in the term "ALK1 Product".
- 1.2 "Affiliate" with respect to either Party, means any corporation or other legal entity other than that Party, in whatever country organized, controlled by, controlling, or under common control with that Party. For the purposes of this definition, the term "control" means (a) for Licensee, (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities or (ii) a fifty percent (50%) or greater interest in the net

assets or profits of a partnership or other business organization without voting securities; and (b) for BIDMC, the power, direct or indirect, to elect or appoint fifty percent (50%) or more of the directors or trustees, or to cause direction of management and policies, whether through the ownership of voting securities, by contract or otherwise.

- 1.3 "Claim" means any pending or issued claim of any Patent Right that has not been permanently revoked, nor held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal, provided that, on a country-by-country and Product-by-Product basis, a patent application pending for more than five (5) years from the priority date of such patent application shall not be considered to be a Claim for purposes of this Agreement from and after such five (5) year date unless and until a patent with respect to such patent application issues.
- 1.4 "<u>First Commercial Sale</u>" means, on a country-by-country basis, the initial Sale to a non-Affiliate third party in a country of a Patented Product following receipt of all regulatory approvals necessary to commence regular commercial scale Sales in such country.
- 1.5 "Field" means all fields of use.
- 1.6 "<u>mTOR-targeted inhibitor</u>" means a direct inhibitor of the protein called the mammalian target of rapamycin. Each of the following compounds is a non-limiting example of an mTOR-targeted inhibitor: everolimus and temsirolimus.
- 1.7 "Net Sales" means:
  - (a) the gross amount billed by Licensee, its Affiliates, and Sublicensees for or on account of Sales of Patented Products, and, for clarity, to the extent that a Patented Product is labeled for a Patented Use and one or more additional uses that are not Patented Uses, only the gross amount billed for or on account of Sales of the Patented Product for the Patented Use shall be deemed to be Net Sales, and, for clarity, Sales for the one or more additional uses shall not be included in Net Sales:

<u>less</u> the following amounts (to the extent appropriately documented) actually paid or otherwise recognized as a revenue reduction by Licensee, its Affiliates, and Sublicensees in effecting such Sale:

- (i) amounts repaid or credited by reason of rejection or return of applicable Patented Products;
- (ii) reasonable and customary trade, quantity or cash rebates or discounts to the extent allowed and taken;
- (iii) amounts for outbound transportation, insurance, handling and shipping, but only to the extent separately invoiced in a manner that clearly specifies the charges applicable to the Patented Products;
- (iv) taxes, customs duties and other governmental charges levied on or measured by Sales of Patented Products, to the extent separately invoiced, whether paid by or on behalf of Licensee, its Affiliates and Sublicensees so long as Licensee's, its Affiliates and Sublicensee's price is reduced thereby, but not franchise or income taxes, or any other tax of any kind whatsoever; and

- (b) Specifically excluded from the definition of "Net Sales" are the following:
  - (i) any amounts billed, invoiced or received attributable to any Sale of any Patented Product between or among Licensee and any Licensee Affiliate and/or Sublicensee, unless the recipient of such transfer is the final purchaser, user or consumer of such Patented Product; and
  - (ii) any Sublicense Income.
- (c) No deductions shall be made for any commissions paid to any individuals or for any costs or expenses of collections.
- (d) Net Sales shall occur, and the applicable Patented Product shall be deemed to have been Sold, on the billing date.
- (e) If Licensee, a Licensee Affiliate, or a Sublicensee Sells any Patented Product for non-cash consideration, Net Sales shall be calculated based on the cash amount charged to an independent third party for the Patented Product during the same Reporting Period or, in the absence of such transaction, on the fair market value of the Patented Product.
- 1.8 "Patent Costs" means all out-of-pocket costs and expenses of any kind, including attorneys' fees, associated with the preparation, filing, prosecution and maintenance of all Patent Rights.
- 1.9 "Patent Challenge" means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Patent Rights or otherwise opposing any of the Patent Rights.
- 1.10 "Patent Rights" means (i) the United States provisional applications listed on Appendix A, and (ii) patent applications that embody additional inventions made by BIDMC pursuant to the MTA which are within the scope of the applications or issued patents at the time included in the Patent Rights and are requested by Licensee at any time to be included as Patent Rights hereunder, and in each case the patents resulting from any of the foregoing applications; any divisions, continuations, and continuations-in-part (but only to the extent the claims are directed to subject matter specifically described in the foregoing patent applications listed in Appendix A and the named inventors are identical to such applications), including foreign patent applications or patents that are equivalent to the foregoing; and any reissues, reexaminations or extensions of any of the foregoing.
- 1.11 "Patented Use" means the use of an ALK1 Product and (i) an RTKI or (ii) an mTOR-targeted inhibitor, for the treatment of patients with renal cell carcinoma. "Patented Use" shall include without limitation the sequential, overlapping or simultaneous dosing of patients with an ALK1 Product and the RTKI or mTOR-targeted inhibitor. "Patented Use" shall also include any additional uses of ALK1 Products that are the subject of a valid Claim of the Licensed Patents.
- 1.12 "Patented Product" means any product (including any apparatus or kit) that
  - (a) in whole or through a component part thereof, the manufacture, use, or sale of which, in the absence of a license from BIDMC, would infringe one or more Claims of the Patent Rights; and
  - (b) is labeled for a Patented Use, as such label is approved by an applicable regulatory authority.

For clarity, the determination of whether a product is considered a Patented Product shall be made on a country-by-country basis in relation to the status of the Patent Rights and any approved label in each country.

- 1.13 "Phase 3 Clinical Trial" means a pivotal clinical trial performed to gain evidence with statistical significance of the efficacy of an ALK1 Product in a target patient population, and to obtain expanded evidence of safety that is needed to evaluate the overall benefit-risk relationship of such ALK1 Product, to form the basis for approval of a New Drug Application or equivalent regulatory approval. In a clinical trial composed of multiple stages (e.g. a phase 2b/3 clinical trial), only that portion of the clinical trial that is named as "phase 3" in the protocol and provides for the enrollment of sufficient numbers of patients to meet the criteria of this definition shall be considered a Phase 3 Clinical Trial.
- 1.14 "Reporting Period" means each three month period ending March 31, June 30, September 30 and December 31.
- 1.15 "RTKI" means a small-molecule receptor tyrosine kinase inhibitor that binds to and inhibits signaling of VEGFR1, VEGFR2, or VEGFR3. An RTKI may, but need not, bind to and inhibit receptor tyrosine kinases in addition to a VEGFR, such as PDGFRa, PDGFRb, RET and c-Met. Likewise, an RTKI may, but need not, inhibit a different class of kinases that are not cell surface receptors, such as the serine kinases B-raf and c-raf kinase. Each of the following compounds is a non-limiting example of an RTKI: sorafenib, pazopanib, axitinib, tivozanib, sunitinib, vandetanib, motesanib, vatalanib and samaxanib.
- 1.16 "Sale" (and "Sell" and "Sold" as the case may be) shall mean to sell or have sold, to lease or have leased, to import or have imported or otherwise to transfer or have transferred a Patented Product for consideration (in the form of cash or otherwise), following receipt of regulatory approval to market such Patented Product or for compassionate use (also referred to as a single-patient IND).
- 1.17 "Sublicense Income" means any payments that Licensee and its Affiliates receive in consideration of the sublicense of, or the grant of an option to receive a sublicense of, the rights granted under Section 2.1, including payments received from entities granted the right to advertise and offer for sale any Patented Products. Such payments include, license fees, milestone payments, and license maintenance fees, but specifically exclude royalties on Net Sales.
- 1.18 "Sublicensee" means any sublicensee of the rights granted to Licensee pursuant to Section 2.1(a).
- 1.19 "Territory" means worldwide.
- 1.20 "Term" means the term of this Agreement, on a country-by-country and Product-by-Product basis, which shall commence on the Effective Date and shall remain in effect until the date on which all claims within the Patent Rights in such country claiming such Patented Product have expired or been abandoned, unless this Agreement is terminated earlier as provided herein.

#### 2. LICENSE

2.1 Grant of License.

- (a) Subject to the terms of this Agreement, BIDMC hereby grants to Licensee and its Affiliates in the Field in the Territory for the Term, an exclusive, royalty-bearing license under BIDMC's rights in the Patent Rights to make, have made, use, have used, Sell, have Sold, import and have imported Patented Products and Patented Uses.
- (b) Subject to the terms of this Agreement and specifically with regards to Section 2.2, BIDMC grants Licensee the right to grant sublicenses under the rights granted in Section 2.1(a), provided that in each case Licensee shall be responsible for the performance of any obligations of Sublicensees relevant to this Agreement as if such performance were carried out by Licensee itself, including, without limitation, the payment of any royalties or other payments provided for hereunder, regardless of whether the terms of any sublicense provide for such amounts to be paid by the Sublicensee directly to BIDMC. For clarity, Licensee shall not be required to pay BIDMC any share of Sublicense Income.
- (c) The foregoing license grants to Licensee Affiliates are subject to each such Affiliate assuming the same obligations as those of Licensee and becoming subject to the same terms and conditions under this Agreement; and further provided that Licensee shall be responsible for the performance of all of such obligations and for compliance with all of such terms and conditions by Affiliate. Licensee shall provide to BIDMC a written list of all Affiliates of Licensee within thirty (30) days of request by BIDMC. Licensee shall cause each of its Affiliates to comply with the provisions and obligations under this Agreement as if such Affiliates were the Licensee.
- 2.2 <u>Sublicenses</u>. Each sublicense granted hereunder shall be consistent with and comply with all applicable terms of this Agreement and shall incorporate terms and conditions sufficient to enable Licensee to comply with this Agreement. Licensee shall provide to BIDMC a fully signed copy of all sublicense agreements and amendments thereto, including all exhibits, attachments and related documents, within thirty (30) days of executing the same; provided that any such copy may be redacted by Licensee to the extent that any such redaction does not impair BIDMC's ability to ensure compliance with this Agreement. Any sublicense which is not in accordance with the forgoing provisions, and is not able to be cured to conform with this Agreement within a commercially reasonable period of time, shall be null and void.

Upon any termination of this Agreement, BIDMC shall automatically be deemed to have entered into a license agreement directly with each Sublicensee on substantially the same terms and conditions under which such sublicenses granted to each Sublicensee by Licensee, provided that (i) such Sublicensee is in material compliance with the Sublicense terms; (ii) such Sublicensee agrees in writing with BIDMC to be bound by the terms, conditions and limitation relating to the licensed Patented Product and Patented Use; and (iii) the terms of any such agreement shall automatically be amended so as not to include obligations upon BIDMC that exceed the obligations of BIDMC under this Agreement.

- 2.3 Retained Rights; Requirements. Any and all licenses granted hereunder are subject to:
  - (a) the royalty-free right of BIDMC and BIDMC's Affiliates and of academic, government and not-for-profit institutions to make, use and/or practice the technology or method described and/or claimed in the Patent Rights for non-commercial, research purposes only; and

- (b) for Patent Rights supported by federal funding, the rights, conditions and limitations imposed by U.S. law (see 35 U.S.C. § 202 et seq. and regulations pertaining thereto), including without limitation:
  - (i) the royalty-free non-exclusive license granted to the U.S. government; and
  - (ii) the requirement that any Patented Products used or sold in the United States shall be manufactured substantially in the United States to the extent required by law, provided that, at Licensee's written request and at Licensee's expense, BIDMC will promptly seek a waiver from the U.S. government with respect to the requirements addressed in this Section 2.3(b)(ii).
- 2.4 <u>No Additional Rights</u>. Nothing in this Agreement shall be construed to grant Licensee an express or implied license under any patent, technology or intellectual property right owned solely or jointly by BIDMC, other than the Patent Rights and Related Information expressly licensed hereunder.

#### 3. DUE DILIGENCE OBLIGATIONS

- 3.1 <u>Diligence Requirements</u>. Licensee shall itself use, or shall cause its Affiliates or Sublicensees, as applicable, to use, commercially reasonable efforts to develop and make available to the public Patented Products throughout the Territory in the Field. Such efforts shall include achieving the following objectives within the time periods designated below following the Effective Date:
  - (a) <u>Pre-Sales Requirements</u>.
    - (i) Within six (6) months after the Effective Date, Licensee shall furnish BIDMC with a written research and development plan, which research and development plan may thereafter be amended by Licensee in its discretion as necessary, describing the major tasks to be achieved in order to bring to market a Patented Product.
    - (ii) By the third (3 <sup>rd</sup>) anniversary of the Effective Date, Licensee (or an Affiliate or Sublicensee) shall initiate a clinical trial for an ALK1 Product in a Patented Use.
    - (iii) By the seventh (7 th) anniversary of the Effective Date, Licensee (or an Affiliate or Sublicensee) shall initiate a Phase 3 Clinical Trial for an ALK1 Product in a Patented Use.
    - (iv) By the twelfth (12 th) anniversary of the Effective Date, Licensee (or an Affiliate or Sublicensee) shall file for regulatory approval to market a Patented Product.
  - (b) <u>Post-Sales Requirements</u>. Following the First Commercial Sale in any country in the Territory, Licensee shall itself or through its Affiliates and/or Sublicensees make continuing Sales in such country without any elapsed time period of one (1) year or more in which such Sales do not occur.
  - (c) <u>Satisfaction of Diligence Obligations</u>; <u>Adjustment of Diligence Obligations</u>. Achievement of the objectives set forth in Sections 3.1(a) and 3.1(b) shall be deemed

to satisfy Licensee's obligations to use commercially reasonable efforts under this Section 3.1. The diligence requirements established in Sections 3.1(a) and 3.1(b) may be adjusted from time to time by written mutual agreement signed by both parties, for example as the case where a regulatory action or requirement causes time to elapse without continuing sales after the First Commercial Sale. In addition, in the event that circumstances beyond Licensee's reasonable control prevent Licensee from meeting its obligations set forth in this Section 3.1, Licensee may so notify BIDMC, and the Parties shall negotiate in good faith an adjustment to the requirements set forth in Section 3.1.

- 3.2 <u>Diligence Failures</u>. If BIDMC determines that any of the obligations under Section 3.1 have not been fulfilled, then BIDMC may treat such failure as a default and may terminate this Agreement in accordance with the terms set forth in Section 10.4.
- 3.3 <u>Diligence Reports</u>. Licensee shall provide all reports with respect to its obligations under Section 3.1 as set forth in Article 5.

#### 4. PAYMENTS AND ROYALTIES

- 4.1 <u>License Issue Fee</u>. Licensee shall pay BIDMC a non-refundable, non-creditable license issue fee in the sum of [\* \* \*] within fifteen (15) days of execution of this Agreement.
- 4.2 <u>Annual License Maintenance Fee</u>. Licensee shall pay to BIDMC the following non-refundable and non-creditable amounts as an annual license maintenance fee within thirty (30) days after each of the following anniversaries of the Effective Date:
  - (a) the first anniversary of the Effective Date: [\* \* \*]; and
  - (b) the second anniversary and on each subsequent anniversary of the Effective Date thereafter: [\* \* \*].

The annual license maintenance fee shall not be due at the end of any year in which a milestone or royalty payment (including minimum annual royalties) is made.

4.3 <u>Milestone Payments</u>. In addition to the payments set forth in Sections 4.1 and 4.2 above, within forty-five (45) days after the date of achievement by Licensee, a Licensee Affiliate or a Sublicensee of the milestones below, Licensee shall pay BIDMC the non-refundable milestone payments indicated. Payments will only be due in respect of the first achievement of the milestone events below for each Patented Product or, as applicable, for an ALK1 Product for a Patented Use. Each such milestone payment shall be payable only one time per Patented Product or, as applicable, per ALK1 Product, and shall not be creditable against any royalties due in the same year.

Pre-Market Milestones

Enrollment of first patient in the first clinical trial initiated after the Effective Date with an ALK1 Product for a Patented Use:

\$ [\*\*\*]

Enrollment of first patient in the second clinical Trial initiated after the Effective Date

with an ALK1 Product for a Patented Use: \$ [\* \* \*]

Enrollment of first patient in the first Phase 3 Clinical Trial with an ALK1 Product for a

Patented Use: \$ [\* \* \*]

<u>Post-Market Milestones</u> <u>Payments</u>

First commercial sale of a Patented Product: \$[\* \* \*]

In the event that BIDMC 1569 inventors Rupal Bhatt or James Mier participate in research directly relating to the subject matter of the Patent Rights during the term of the Agreement, Licensor shall so inform Licensee and pre-market milestone payments thereafter due shall be waived from that timepoint forward, and the post-market milestone payment due upon first commercial sale of a Patented Product shall change from \$[\* \* \*] to the sum of \$[\* \* \*] plus any waived milestone payments.

#### 4.4 Royalties.

- (a) Beginning with the First Commercial Sale in any country in the Territory, Licensee shall pay BIDMC a royalty of one and one half percent (1.5%) on Net Sales in such country.
- (b) Within thirty (30) days after the first anniversary of the first event of a First Commercial Sale in any country and on each subsequent anniversary of such First Commercial Sale thereafter, Licensee shall pay to BIDMC twenty-five thousand U.S. dollars (\$25,000) as a non-refundable minimum annual royalty, payable only once per year, regardless of the number of countries in which the Product is sold; such annual minimum royalty shall be credited against royalties subsequently due on Net Sales, if any, made during the same calendar year, but shall not be credited against royalties due on Net Sales, if any, made in any other year.
- (c) All payments due to BIDMC under this Section 4 shall be due and payable by Licensee within sixty (60) days after the end of each Reporting Period, and shall be accompanied by a report as set forth in Section 5.3.
- 4.5 Form of Payment. All payments due under this Agreement shall be drawn on a United States bank and shall be payable in United States dollars. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment satisfies. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States, as reported in The Wall Street Journal, on the last working day of the applicable Reporting Period. To the extent that Licensee is required to deduct and withhold taxes on any payments to BIDMC, Licensee shall pay the amounts of such taxes to the proper governmental authority in a timely manner and transmit to BIDMC in a timely manner an official tax certificate or other evidence of such withholding sufficient to enable BIDMC to claim such payments of taxes. BIDMC shall provide to Licensee any tax forms that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other Party with reasonable assistance to enable the recovery, as permitted by law, of withholding

taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or VAT. Checks for all payments due to BIDMC under this Agreement shall be made payable to BIDMC and addressed as set forth in Section 13.2.

- 4.6 Overdue Payments. The payments due under this Agreement shall, if overdue, bear interest at two percentage points above the Prime Rate of interest as reported in the Wall Street Journal on the date payment is due until payment thereof, not to exceed the maximum permitted by law. Any such overdue payments when made shall be accompanied by all interest so accrued. Payment and acceptance, in whole or in part, of interest and the overdue payment shall not preclude BIDMC from exercising any other rights it may have as a consequence of the lateness of any payment. Any payment that is subject to a bona fide dispute shall not be subject to this Section 4.6 for the time that the parties are attempting, in good faith, to resolve such dispute.
- 4.7 <u>Consequences of a Patent Challenge</u>. In the event that (a) Licensee, any of its Affiliates, or any Sublicensee brings a Patent Challenge against BIDMC, or (b) Licensee, any of its Affiliates, or any Sublicensee assists another party in bringing a Patent Challenge against BIDMC (except as required under a court order or subpoena), and, in either such case, BIDMC does not choose to exercise its rights to terminate this Agreement pursuant to Section 10.5, then if such a Patent Challenge is successful, Licensee will have no right to recoup any monies paid during the period of challenge.

#### 5. REPORTS AND RECORDS

- 5.1 <u>Diligence Reports</u>. Within thirty (30) days after the end of each calendar year, Licensee shall report in writing to BIDMC on progress made toward the due diligence obligations set forth in Section 3.1 during such preceding 12 month period, including, without limitation, progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing and the number of sublicenses entered into and marketing.
- 5.2 <u>Milestone Achievement Notification</u>. Licensee shall report to BIDMC the dates on which it achieves the milestones set forth in Section 4.3 within forty-five (45) days of each such occurrence.
- 5.3 <u>Sales Reports</u>. Licensee shall report to BIDMC the date on which it achieves the First Commercial Sale in each country of the Territory within thirty (30) days of each such occurrence. Following the First Commercial Sale, Licensee shall deliver reports to BIDMC within sixty (60) days after the end of each Reporting Period. Each report under this Section 5.3 shall have substantially the format outlined in Appendix B, shall be certified as correct by an officer of Licensee and shall contain at least the following information as may be pertinent to a royalty accounting hereunder for the immediately preceding Reporting Period:
  - (a) the number of Patented Products Sold by Licensee, its Affiliates, and Sublicensees in each country;
  - (b) the amounts billed, invoiced and received by Licensee, its Affiliates, and Sublicensees for each Patented Product, in each country, and total billings or payments due or made for all Patented Products;

- (c) calculation of Net Sales for the applicable Reporting Period in each country, including an itemized listing of permitted offsets and deductions;
- (d) total royalties payable on Net Sales in U.S. dollars, together with the exchange rates used for conversion; and
- (e) any other payments due to BIDMC under this Agreement.

If no amounts are due to BIDMC for any Reporting Period, the report shall so state.

Audit Rights. Licensee shall maintain, and shall cause each of its Affiliates and Sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to BIDMC in relation to this Agreement, which records shall contain sufficient information to permit BIDMC and its representatives to confirm the accuracy of any payments and reports delivered to BIDMC and compliance in all other respects with this Agreement. Licensee shall retain and make available, and shall cause each of its Affiliates and Sublicensees to retain and make available, such records for at least five (5) years following the end of the calendar year to which they pertain, to BIDMC and/or its representatives, at BIDMC's expense and upon at least fifteen (15) days' advance written notice, for inspection during normal business hours. If any examination conducted by BIDMC or its representatives pursuant to the provisions of this Section show an underreporting or underpayment of five percent (5%) or more, Licensee shall bear the full cost of such audit and shall remit any amounts due to BIDMC (including interest due in accordance with Section 4.6) within thirty (30) days of receiving notice thereof from BIDMC.

#### 6. PATENT PROSECUTION AND MAINTENANCE

6.1 <u>Prosecution</u>. Provided that Licensee seeks and maintains the strongest and broadest reasonable patent claims in the best interests of all owners of the Patent Rights and uses patent attorneys acceptable to BIDMC, such acceptance not to be unreasonably withheld, BIDMC appoints Licensee as its agent to prepare, file, prosecute, and maintain all of the Patent Rights during the Term. Licensee shall pay Licensee's patent counsel directly for any invoiced Patent Costs and agrees to indemnify, defend and hold BIDMC harmless from and against any and all liabilities, damages, costs and expenses incurred by or imposed upon BIDMC in connection with any third party claim arising from the failure of Licensee to timely pay such invoices. Licensee shall instruct patent counsel to provide copies to BIDMC for BIDMC's administrative files of all invoices detailing Patent Costs which are sent directly to Licensee and inform patent counsel that in no case shall BIDMC be liable for any Patent Costs incurred at the instruction of Licensee. Licensee shall copy BIDMC on all patent prosecution documents and give BIDMC reasonable opportunities to advise Licensee on such filing, prosecution and maintenance.

In the event Licensee desires to abandon any patent, patent application, or any patent claims within the Patent Rights, Licensee shall provide BIDMC with reasonable prior written notice of such intended abandonment. If Licensee determines to abandon such patent or patent application without filing a divisional or continuing application directed to similar subject matter, then, at its sole discretion, BIDMC may assume the right to prepare, file, prosecute and maintain the relevant Patent Rights at BIDMC's expense. In such event, if such abandonment is in the European Union., United States or Japan, such BIDMC paid-for rights shall be removed from the definition of Patent Rights under this Agreement, the licenses granted to Licensee and its Affiliates as to such rights under this Agreement shall terminate, except that, for the avoidance of doubt, Licensee shall retain the rights as set forth in the MTA, and BIDMC shall have the right to abandon or maintain and license its interest

in such Patent Rights in its discretion. In the event Licensee (i) fails to maintain any of the Patent Rights and has not complied with the last sentence of the first paragraph of this Section 6.1, or (ii) fails to notify BIDMC of its intent to abandon such Patent Rights, in accordance with this Section, Licensee shall indemnify, defend and hold BIDMC harmless from and against costs and liabilities to any third parties that are associated with the recovery of or loss of any such Patent Rights.

In the event that License is obligated to indemnify BIDMC pursuant to this Section 6.1, such indemnification obligation shall be on the term set forth in Section 8.1.

- 6.2 <u>Copies of Documents</u>. With respect to any Patent Right licensed hereunder, Licensee shall instruct the patent counsel prosecuting such Patent Right to (i) copy BIDMC on patent prosecution documents that are received from or filed with the United States Patent and Trademark Office and foreign equivalent, as applicable; (ii) if requested by BIDMC, provide BIDMC with copies of draft submissions to the USPTO prior to filing; and (iii) give consideration to the comments and requests of BIDMC or its patent counsel.
- 6.3 <u>Licensee's Election Not to Proceed</u>. Licensee may elect to surrender any patent or patent application, on a country-by-country or Patent-by-Patent basis, in Patent Rights in any country upon sixty (60) days advance written notice to BIDMC. Notwithstanding such election to surrender any such patent or patent application, for the avoidance of doubt, Licensee shall retain all rights under the MTA. Such notice shall relieve Licensee from the obligation to pay for future Patent Costs but shall not relieve Licensee from responsibility to pay Patent Costs incurred prior to the expiration of the sixty (60) day notice period. Such U.S. or foreign patent application or patent shall thereupon cease to be a Patent Right hereunder and BIDMC shall be free to license its rights to that particular U.S. or foreign patent application or patent to any other party on any terms. For the avoidance of doubt, nothing in this Article 6 shall be interpreted as abrogating any rights Licensee may have with regard to the Patent Rights by virtue of joint ownership therein.
- 6.4 <u>Confidentiality of Prosecution and Maintenance Information</u>. Each Party agrees to treat all information related to prosecution and maintenance of Patent Rights as Confidential Information in accordance with the provisions of Appendix C.

#### 7. THIRD PARTY INFRINGEMENT AND LEGAL ACTIONS

- 7.1 <u>Licensee Right to Prosecute</u>. Licensee shall have the first right, but not the obligation, to initiate legal proceedings to protect the Patent Rights from infringement, with respect to a claim of a Patent Right in the Field in the Territory, and prosecute infringers at Licensee's expense. Before commencing such action, Licensee and, as applicable, any Affiliate, shall consult with BIDMC concerning the advisability of bringing suit, the selection of counsel and the jurisdiction for such action (provided Licensee must have BIDMC's prior written consent, such consent to not be unreasonably withheld, conditioned or delayed, with respect to selection of jurisdiction for any action in which BIDMC may be joined as a party-plaintiff) and shall consider the views of BIDMC regarding the proposed action, especially but without limitation with respect to potential effects on the public interest.
- 7.2 <u>BIDMC Right to Prosecute</u>. In the event that Licensee elects not to take action pursuant to this Section 7.1, Licensee shall so notify BIDMC promptly in writing of its intention in good time to enable BIDMC to meet any deadlines by which an action must be taken to establish or preserve any enforcement rights, and BIDMC shall have the right to take steps to protect the Patent Rights from infringement, with respect to a claim of a Patent Right in the Field in the Territory, and prosecute

infringers at BIDMC's expense. If BIDMC notifies Licensee that it intends to so prosecute, BIDMC shall use reasonable efforts, within three (3) months of its notice to Licensee, to (i) cause such infringement to terminate; (ii) reach a settlement with infringer; or (iii) initiate legal proceedings against the infringer. Nothing in this Section 7.2 shall be construed to prevent Licensee from initiating legal proceedings, in accordance with their independent judgment of the merits of an infringement action, as provided in Section 7.1.

- 7.3 <u>BIDMC Joining as a Party-Plaintiff</u>. If Licensee elects to commence an action as described in Section 7.1 above, BIDMC shall have, in its sole discretion and at its own expense, the option to voluntarily join such action as a party-plaintiff.
- 7.4 <u>Notice of Actions; Settlement</u>. Licensee shall promptly inform BIDMC of any action or suit relating to Patent Rights and shall not enter into any settlement, consent judgment or other voluntary final disposition of any action relating to Patent Rights, including but not limited to appeals, that imposes any liability on BIDMC or binds BIDMC to any contractual relationship or admits the invalidity or unenforceability of any Patent Rights, without the prior written consent of BIDMC, which shall not be unreasonably withheld or delayed.
- 7.5 <u>Cooperation</u>. If necessary to enable any enforcement action undertaken by either Party, the Parties agree to be joined as parties to such enforcement action. Each Party agrees to cooperate reasonably in any action under this Article 7 which is controlled by the other Party, provided that the controlling party reimburses the cooperating party for any costs and expenses incurred by the cooperating party in connection with providing such assistance, except for the expense of any independent counsel retained by BIDMC in accordance with Section 7.3. Such controlling party shall keep the cooperating party informed of the progress of such proceedings and shall make its counsel available to the cooperating party. The cooperating party shall also be entitled to independent counsel in such proceedings but at its own expense, said expense to be offset against any damages received by the Party bringing suit in accordance with Section 7.6.
- 7.6 Recovery. Any award paid by third parties as the result of such proceedings (whether by way of settlement or otherwise) shall first be applied to reimbursement of any legal fees and expenses incurred by both Parties, in proportion to their expenditures, and then the remainder, if any, shall be distributed between the Parties as follows [provided however that in any award paid by third parties as a result of a settlement or other dispute resolution that does not result in a finding of infringement and damages calculated in a manner described in part (a)(i) below, all payments shall be deemed to be of the type described in part (a)(i) below and BIDMC shall receive only the amount provided in part (a)(ii) below]:
  - (a) (i) Licensee shall receive an amount equal to its lost profits or a reasonable royalty on the infringing sales, or whichever measure of damages the court shall have applied; and
    - (ii) BIDMC shall receive an amount equal to the royalties and other amounts that Licensee would have paid to BIDMC if Licensee had Sold the infringing Patented Products rather than the infringer; and
  - (b) only in the case of a decision of patent infringement in which damages are calculated in a manner described in Part(a) (i) above, the balance, if any, remaining after Licensee and BIDMC have been compensated under Section 7.6(a), shall be shared *pro rata*. To

determine BIDMC's pro rata distribution, the balance will be multiplied by the following fractions:

- (i) the number of patents within the Patent Rights found to be enforceable and infringed divided by the total number of patents in suit found to be enforceable and infringed; and
- (ii) the number of BIDMC inventors divided by all inventors named in the relevant Licensed Patents.

#### 8. INDEMNIFICATION AND INSURANCE

#### 8.1 Indemnification.

- (a) Licensee shall indemnify, defend and hold harmless BIDMC and its Affiliates and their respective trustees, directors, officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss or expense (including reasonable attorney's fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any third party claims, suits, actions, demands or judgments arising out of any theory of liability, including without limitation, any theory of product liability (including, but not limited to, actions in the form of contract, tort, warranty, or strict liability) concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement.
- (b) BIDMC shall endeavor to promptly notify Licensee in writing for any claim of indemnification hereunder. Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to the BIDMC to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought; provided, however, that any Indemnitee shall have the right to retain its own counsel, at the expense of Licensee, if Licensee's defense of such claim by counsel retained by Licensee would create an actual or potential conflict of interest. Licensee agrees to keep BIDMC informed of the progress in the defense and disposition of such claim and to consult with BIDMC prior to any proposed settlement. For purposes of clarity, Licensee shall manage the defense it underwrites for the claim of indemnification hereunder and shall be relieved of its indemnification obligation to the extent a delay by BIDMC in notifying Licensee materially impairs the Licensee's ability to defend such a claim.
- (c) This Section 8.1 shall survive expiration or termination of this Agreement.

#### 8.2 <u>Insurance</u>.

(a) Beginning at such time as any such product, process or service is being commercially distributed, sold, leased or otherwise transferred, or performed or used (other than for the purpose of obtaining regulatory approvals), by Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for the indemnification

obligations under Section 8.1 of this Agreement. Licensee may not elect to self-insure without (a) providing to BIDMC certification of adequate insurance and (b) securing BIDMC's written approval, such approval not to be unreasonably withheld. The minimum amounts of insurance coverage required under this Section 8.2 shall not be construed to create a limit of liability with respect to the indemnification obligations under Section 8.1 of this Agreement.

- (b) Licensee shall provide BIDMC with written evidence of such insurance upon request of BIDMC. Licensee shall provide BIDMC with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage prior to the expiration of such fifteen (15) day period, BIDMC shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.
- (c) Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any such product, process or service is being commercially distributed, sold, leased or otherwise transferred, or performed or used (other than for the purpose of obtaining regulatory approvals), by Licensee or by a licensee, affiliate or agent of Licensee and (ii) a reasonable period after the period referred to in (c) (i) above which in no event shall be less than ten (10) years.
- (d) This Section 8.2 shall survive expiration of termination of this Agreement.
- 8.3 <u>Affiliates and Sublicensees</u>. Licensee shall require all its Affiliates and Sublicensees to comply with the provisions and obligations under this Article 8 as if such entity were the Licensee.

#### 9. DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITY

- 9.1 No Warranties . BIDMC HEREBY DISCLAIMS AND MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE PATENT RIGHTS AND ANY OF THE RIGHTS GRANTED HEREUNDER, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OF PATENT RIGHTS CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. SPECIFICALLY, AND NOT TO LIMIT THE FOREGOING, BIDMC MAKES NO WARRANTY OR REPRESENTATION (i) REGARDING THE VALIDITY OR SCOPE OF ANY OF THE CLAIM(S), WHETHER ISSUED OR PENDING, OF ANY OF THE PATENT RIGHTS, AND (ii) THAT THE EXPLOITATION OF THE PATENT RIGHTS OR ANY PATENTED PRODUCT OR PROCESS WILL NOT INFRINGE ANY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF BIDMC OR OF ANY THIRD PARTY.
- 9.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY OR ANY OF THEIR AFFILIATES OR ANY OF THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, MEDICAL AND PROFESSIONAL STAFF, EMPLOYEES AND AGENTS BE LIABLE TO THE OTHER PARTY OR ANY OF THEIR AFFILIATES OR SUBLICENSEES FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE LICENSE RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER THE APPLICABLE PARTY SHALL BE ADVISED, SHALL

HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

### 10. TERM AND TERMINATION

- 10.1 <u>Expiration of Agreement</u>. This Agreement shall expire on a country-by-country and Patented Product-by-Patented Product basis at the end of the applicable Term, at which time the License in such country with respect to such Patented Product shall be fully paid, irrevocable and perpetual.
- 10.2 <u>Termination for Failure to Pay</u>. If Licensee fails to make any payment due hereunder, BIDMC shall have the right to terminate this Agreement upon fifteen (15) business days written notice, unless Licensee makes such payments plus any interest due, as set forth in Section 4.6, within said fifteen (15) day notice period. If payments are not made, BIDMC may immediately terminate this Agreement at the end of said fifteen (15) day period.
- 10.3 <u>Termination for Insurance and Insolvency</u>. BIDMC may terminate this Agreement immediately upon written notice with no further notice obligation or opportunity to cure if Licensee fails to maintain or replace the insurance required by Section 8.2 or if Licensee shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it.
- Termination for Non-Financial Default. If Licensee, any of its Affiliates, or any Sublicensee shall default in the performance of any of its obligations under this Agreement (excluding as provided for in Sections 10.2 and 10.3), including but not limited to its obligations under Section 3.1(b), and if such default has not been cured within sixty (60) days after notice by BIDMC in writing of such default, then at the end of such cure period, BIDMC may, at its option, in its sole discretion, either (i) terminate any licenses granted hereunder with respect to the country or countries in which such default has occurred, or (ii) terminate the Agreement in its entirety; provided that, if such default is a default of Licensee's obligations under Section 3.1(b), then BIDMC may only terminate the licenses granted hereunder pursuant to clause (i) with respect to the country or countries in which such default has occurred. Notwithstanding the foregoing, if any default by Licensee cannot reasonably be cured within the sixty (60) day period described in the preceding sentence, and Licensee within such sixty (60) day period provides BIDMC with a plan to cure such default, BIDMC may not terminate all or any portion of this Agreement as a result of such default so long as Licensee continues to use commercially reasonable efforts to cure such default in accordance with such plan. All cure periods arising under this Section 10.4 shall be tolled during the pendency of any bona fide dispute regarding the occurrence of a default by Licensee.
- 10.5 <u>Patent Challenge</u>. During the Term:
  - (a) If Licensee or any of its Affiliates brings a Patent Challenge against BIDMC, or assists others in bringing a Patent Challenge against BIDMC (except as required under a court order or subpoena), then BIDMC may immediately terminate this Agreement and/or the license granted hereunder.
  - (b) If a Sublicensee brings a Patent Challenge or assists another party in bringing a Patent Challenge (except as required under a court order or subpoena), then BIDMC may send a written demand to Licensee to terminate such sublicense agreement. If Licensee fails to so terminate such sublicense within thirty (30) days after BIDMC's demand, or cause

Sublicensee to terminate such Patent Challenge, BIDMC may immediately terminate this Agreement and/or any licenses granted hereunder.

- 10.6 <u>Termination by Licensee</u>. Licensee shall have the right to terminate this Agreement by giving ninety (90) days advance written notice to BIDMC
- 10.7 Effects of Termination of Agreement.
  - (a) <u>General</u>. Upon termination of this Agreement or any of the licenses hereunder for any reason, final reports in accordance with Article 5 shall be submitted to BIDMC and all royalties and other payments, including without limitation any unreimbursed Patent Costs, accrued or due to BIDMC as of the termination date shall become immediately payable. The termination or expiration of this Agreement or any licenses granted hereunder shall not relieve Licensee, its Affiliates or Sublicensees of obligations arising before such termination or expiration. The terms of the MTA shall survive any termination of this Agreement, including all licenses granted by BIDMC to Licensee thereunder. For the avoidance of doubt, no termination of this Agreement shall abrogate any rights Licensee may have with regard to the Patent Rights by virtue of joint ownership therein.
  - (b) <u>Survival</u>. The following provisions shall survive the expiration or termination of this Agreement: Articles 1, 4 (to the extent relevant to final Sales), 5, 8, 9 and 12 and Section 10.7.

#### 11. COMPLIANCE WITH LAW

11.1 <u>Compliance</u>. Licensee shall have the sole obligation for compliance with, and shall ensure that any Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Patented Products, including, but not limited to, those of the Food and Drug Administration and the Export Administration, and any applicable laws and regulations of any other country in the Territory. Licensee agrees that it shall be solely responsible for obtaining any necessary licenses to export, re-export, or import Patented Products covered by Patent Rights and/or Confidential Information and that it will indemnify, defend, and hold BIDMC harmless (in accordance with Section 8.1) for the consequences of any violation by Licensee, its Affiliates or Sublicensees of any such laws or regulations.

## 12. ASSIGNMENT

Assignment. This Agreement is personal to Licensee and no rights or obligations may be assigned by Licensee without the prior written consent of BIDMC, except that Licensee may assign its rights and obligations under this Agreement to an Affiliate or to a successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or equity or that portion of its business to which this Agreement relates ("Assignment"); provided, however, that (i) this Agreement shall immediately terminate if the proposed assignee fails to agree in writing to be bound by the terms and conditions of this Agreement on or before the effective date of the Assignment; and (ii) Licensee shall pay to BIDMC on or before the effective date of the Assignment a fee in the amount of ten thousand U.S. dollars (\$10,000). Licensee shall provide a copy of all assignment documents and related agreements to BIDMC within thirty (30) days of such Assignment.

#### 13. MISCELLANEOUS

- 13.1 <u>Entire Agreement</u>. This Agreement and the MTA constitutes the entire understanding between the Parties with respect to the subject matter hereof.
- Notices. Any notice, communication or payment required or permitted to be given or made hereunder shall be in writing and, except as otherwise expressly provided in this Agreement, shall be deemed given or made and effective (i) when delivered personally; or (ii) when delivered by telex or telecopy(if not a payment); or (iii) when received if sent by overnight express or mailed by certified, registered or regular mail, postage prepaid, addressed to parties at their address stated below, or to such other address as such party may designate by written notice in accordance with the provisions of this Agreement.

BIDMC: Attn: Mark Chalek

Chief, Business Ventures

Beth Israel Deaconess Medical Center

330 Brookline Avenue, FN2

Boston, MA 02215 Fax # 617-667-0537

With a copy to: General Counsel

Legal Department CareGroup, Inc.

109 Brookline Avenue, Suite 300

Boston, MA 02215

LICENSEE: Acceleron Pharma, Inc.

Attn: Dr. John Knopf Chief Executive Officer

128 Sidney Street Cambridge, MA 02139

Fax # 617-649-9988

With a copy to: Ropes & Gray LLP

Attn: Marc Rubenstein

800 Boylston St., Prudential Tower

Boston, MA 02199 Fax # 617-235-0706

- Amendment; Waiver. This Agreement may be amended and any of its terms or conditions may be waived only by a written instrument executed by an authorized signatory of the Parties or, in the case of a waiver, by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a further or continuing waiver of such condition or term or of any other condition or term. Notwithstanding the foregoing, except for disputes relating to errors of fact of the type that may be discovered in an audit pursuant to Section 5.4, neither Party may dispute a payment made hereunder more than six (6) months after the date such payment is accepted by the payee.
- 13.4 <u>Binding Effect</u>. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

- 13.5 <u>Force Majeure</u>. Neither Party shall be responsible for delays resulting from fire, explosion, flood, war, sabotage, strike or riot, or similar causes beyond the reasonable control of such Party, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.
- 13.6 <u>Use of Name</u>. Neither Party shall use the name of the other Party or of any trustee, director, officer, staff member, employee, student or agent of the other Party or any adaptation thereof in connection with the activities contemplated under this Agreement in any advertising, promotional or sales literature, publicity or in any document employed publicly to obtain funds or financing without the prior written approval of the Party or individual whose name is to be used. Nothing in this Section 13.6 shall prevent either Party from providing appropriate scientific citation in any public document.
- 13.7 Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts, excluding with respect to conflict of laws, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Each Party agrees to submit to the exclusive jurisdiction of the Superior Court for Suffolk County, Massachusetts, and the United States District Court for the District of Massachusetts with respect to any claim, suit or action in law or equity arising in any way out of this Agreement or the subject matter hereof.
- 13.8 <u>BIDMC Policies</u>. Licensee acknowledges that BIDMC's employees and medical and professional staff members and the employees and staff members of BIDMC's Affiliates are subject to the applicable policies of BIDMC and such Affiliates, including, without limitation, policies regarding conflicts of interest, intellectual property and other matters. BIDMC shall provide Licensee, at Licensee's request, with copies of any such policies applicable to any such employee or staff member.
- 13.9 <u>Severability</u>. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the term hereof, it is the intention of the parties that the remainder of this agreement shall not be effected thereby. It is further the intention of the parties that in lieu of each such provision which is invalid, illegal or unenforceable, there be substituted or added as part of this Agreement a provision which shall be as similar as possible in economic and business objectives as intended by the parties to such invalid, illegal or enforceable provision, but shall be valid, legal and enforceable.
- 13.10 <u>Interpretation</u>. The parties hereto are sophisticated, have had the opportunity to consult legal counsel with respect to this transaction and hereby waive any presumptions of any statutory or common law rule relating to the interpretation of contracts against the drafter.
- 13.11 Headings. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement.
- 13.12 Dispute Resolution.
  - (a) Subject to Section 13.3 and 13.12(b) below, if a dispute arises between the Parties relating to the interpretation or performance of this Agreement or the grounds for the termination thereof, the Parties agree to hold a meeting, attended by individuals with

decision-making authority regarding the dispute, to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If the dispute remains unresolved sixty (60) days after the above-mentioned meeting, then each party shall have the right to pursue other remedies legally available to resolve the dispute.

- (b) Subject to Section 13.3, in the event that the BIDMC disputes Licensee's calculation of Net Sales for a Patented Product that is labeled for a Patented Use and one or more additional uses that are not Patented Uses, BIDMC shall promptly notify Licensee in writing and shall provide Licensee with an alternative calculation of Net Sales. The Parties shall negotiate in good faith to resolve the dispute for a period of sixty (60) days from the date on which Licensee provides its alternative calculation. If the dispute remains unresolved at the end of the negotiation period, then the Parties agree to resolve the dispute as follows: each Party will select a qualified expert with experience in the valuation of pharmaceutical products, and the two experts selected in this manner will select a third qualified expert, provided that the third expert shall have no conflicts of interest regarding either Party. After consideration of available information that is reasonably pertinent to the dispute, such information to be kept confidential by the experts and the Parties, the three experts will determine the appropriate calculation of the disputed Net Sales and the Parties will abide by this determination. The three experts will also determine an appropriate methodology for the calculation of future Net Sales to the extent any subsequent dispute regarding Net Sales involves similar issues as the previously resolved dispute. The Parties will share equally the costs incurred in connection with the valuation experts.
- (c) Subject to Section 13.3, in the event that a dispute involves a claim of breach or default under Section 10.2 or Section 10.4, then the applicable cure period under such Section shall be tolled during the pendency of any dispute in accordance with this Section 13.12.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

BETH ISRAEL DEACONESS MEDICAL CENTER

The Effective Date of this License Agreement is Jun 21, 2012.

ACCELERON PHARMA, INC.

,			
BY: /s/ John Knopf Name: Name:	BY:/s/ Mark Chalek	_	
TITLE:CEO	TITLE: Chief, Technology Ventures		
DATE:11/21/12	DATE: <u>11/5/12</u>	_	

## Appendix A

## **DESCRIPTION OF PATENT RIGHTS**

Provisional patent applications associated with BIDMC case [\* \* \*]

## Appendix B

## **COMMERCIAL SALES REPORTS**

## AGREEMENT INCOME REPORT Fees, Milestones and Sublicense Income

Agreement # - Licensee - Sub-Licensee -		

Separate reports must be filed for Payments associated with each Patented Product:

**Product Name:** 

**Report Time Period:** 

From mm/dd/yyyy

To mm/dd/yyyy

PLEASE ATTACH DETAIL AS REQUIRED

## AGREEMENT INCOME REPORT Royalty Income

Agreement # -	
Licensee -	
Sub-Licensee -	

Separate reports must be filed for:

- 1. Each Product sold.
- 2. Each country of sale, if different deductions or royalty rates apply.

#### **Product Name:**

### **Report Time Period:**

From mm/dd/yyyy

To mm/dd/yyyy

## Country of Sale

**Quantity Sold** 

Net Sales (USD) \$ \$

Exchange Rate

## Deductions and Credits (Itemize)

Please list each deduction and credit separately.

Use same definition as appears in Agreement and include the contract paragraph as a reference.

## Royalty Percentage

Royalty Due \$ \$

PLEASE ATTACH DETAIL SALES REPORTS AS REQUIRED

## **APPENDIX C**

#### CONFIDENTIALITY TERMS AND CONDITIONS

The following provisions under this Appendix C shall only apply to the Patent Prosecution and Maintenance Information requirements under Section 6,

- 1. <u>Definition of Confidential Information</u>. "Confidential Information" shall mean any information, including but not limited to data, techniques, protocols or results, or business, financial, commercial or technical information, disclosed by one Party (each a "Discloser" as applicable) to the other Party (each a "Recipient" as applicable) in connection with the terms of that certain Exclusive License Agreement effective as of the Effective Date (the "License Agreement") and identified as confidential at the time of disclosure (the "Purpose"). BIDMC's Confidential Information shall also include all information disclosed by BIDMC to Licensee in connection with the Patent Rights. Capitalized terms used in this Appendix that are not otherwise defined herein have the meanings ascribed in the License Agreement to which this Appendix is attached and made a part thereof.
- 2. Exclusions. "Confidential Information" under this Agreement shall not include any information that (i) is or becomes publicly available through no wrongful act of Recipient; (ii) was known by Recipient prior to disclosure by Discloser, as evidenced by tangible records; (iii) becomes known to Recipient after disclosure from a third party having an apparent bona fide right to disclose it; (iv) is independently developed or discovered by Recipient without use of Discloser's Confidential Information, as evidenced by tangible records; or (v) is disclosed to another party by Discloser without restriction on further disclosure. The obligations of confidentiality and non-use set forth in this Agreement shall not apply with respect to any information that Recipient is required to disclose or produce pursuant to applicable law, court order or other valid legal process provided that Recipient promptly notifies Discloser prior to such required disclosure, discloses such information only to the extent so required and cooperates reasonably with Discloser's efforts to contest or limit the scope of such disclosure.
- 3. <u>Permitted Purpose</u>. Recipient shall have the right to, and agrees that it will, use Discloser's Confidential Information solely for the Purpose as described in the License Agreement, except that Acceleron shall be permitted to share the Confidential Information with investors, potential investors, lenders, potential lendors, licensees, potential licensees and potential Sublicensees provided that each third party to whom the Confidential Information is disclosed shall have entered into a written obligation of confidentiality and non-use with Acceleron that is at least as stringent as the obligations set forth in this Appendix C.
- 4. <u>Restrictions</u>. For the term of the License Agreement and a period of three (3) years thereafter (and indefinitely with respect to any individually identifiable health information disclosed by BIDMC to Licensee, if any), each Recipient agrees that: (i) it will not use such Confidential Information for any purpose other than as specified herein, including without limitation for its own benefit or the benefit of any other person or entity; and (ii) it will use reasonable efforts (but no less than the efforts used to protect its own confidential and/or

proprietary information of a similar nature) not to disclose such Confidential Information to any other person or entity except as expressly permitted hereunder. Recipient may, however, disclose Discloser's Confidential Information only on a need-to-know basis to its and its Affiliates employees, staff members and agents ("Receiving Individuals") who are directly participating in the Purpose and who are informed of the confidential nature of such information, provided Recipient shall be responsible for compliance by Receiving Individuals with the terms of this Agreement and any breach thereof. Each party further agrees not to use the name of the other party or any of its Affiliates or any of their respective trustees, directors, officers, staff members, employees, students or agents in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the party or individual whose name is to be used, in the case of BIDMC such approval to be given by the Public Affairs Department. This Section 4 shall survive termination or expiration of this Agreement.

- 5. <u>Right to Disclose</u>. Discloser represents that to the best of its knowledge it has the right to disclose to each Recipient all of Discloser's Confidential Information that will be disclosed hereunder.
- 6. Ownership. All Confidential Information disclosed pursuant to this Agreement, including without limitation all written and tangible forms thereof, shall be and remain the property of the Discloser. Upon termination of this Agreement, if requested by Discloser, Recipient shall return or destroy at Discloser's discretion all of Discloser's Confidential Information, provided that Recipient shall be entitled to keep one copy of such Confidential Information in a secure location solely for the purpose of determining Recipient's legal obligations hereunder.
- 7. <u>No License</u>. Nothing in this Agreement shall be construed as granting or conferring, expressly or impliedly, any rights by license or otherwise, under any patent, copyright, or other intellectual property rights owned or controlled by Discloser relating to Confidential Information, except as specifically set forth in the License Agreement.
- 8. <u>Remedies</u>. Each party acknowledges that any breach of this Agreement by it may cause irreparable harm to the other party and that each party is entitled to seek injunctive relief and any other remedy available at law or in equity.
- 9. <u>General</u>. These Confidentiality Terms and Conditions, along with the License Agreement, contain the entire understanding of the parties with respect to the subject matter hereof, and supersede any prior oral or written understandings between the parties relating to confidential treatment of information. Sections 1, 2, 4, 7, 10 and 11 of these Confidentiality Terms and Conditions shall survive any expiration or termination of the License Agreement.

#### CERTIFICATION OF CHIEF EXECUTIVE OFFICER, ACCELERON PHARMA INC.

#### I, John L. Knopf, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Acceleron Pharma 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(s) 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(s) 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 function):
  - 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.

August 4, 2016 /s/ John L. Knopf, Ph.D.

Date

John L. Knopf, Ph.D. Chief Executive Officer and President (Principal Executive Officer)

#### CERTIFICATION OF CHIEF FINANCIAL OFFICER, ACCELERON PHARMA INC.

#### I, Kevin F. McLaughlin, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Acceleron Pharma 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(s) 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(s) 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 function):
  - 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.

August 4, 2016 /s/ Kevin F. McLaughlin

Date Kevin F. McLaughlin

Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Acceleron Pharma Inc. (the "Company") for the period ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 4, 2016 By: /s/ John L. Knopf, Ph.D.

John L. Knopf, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

Date: August 4, 2016 By: /s/ Kevin F. McLaughlin

Kevin F. McLaughlin

Senior Vice President, Chief Financial Officer and Treasurer

(Principal Financial Officer)