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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from to

Commission File Number: 001-36065

ACCELERON PHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**27-0072226**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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)

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

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

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

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

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

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

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

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

As of July 31, 2021, there were 60,900,521 shares of the registrant's Common Stock, par value $0.001 per 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 336,199	$ 670,952
Short-term investments	287,151	178,951
Collaboration receivables (all amounts are with a related party)	27,937	26,101
Prepaid expenses and other current assets	66,486	17,265
Total current assets	717,773	893,269
Property and equipment, net	8,580	7,768
Operating lease - right of use asset, net	18,799	21,988
Long-term investments	89,194	7,585
Other assets	1,706	1,727
Total assets	$ 836,052	$ 932,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,438	$ 8,472
Accrued expenses	42,488	44,681
Operating lease liability - right of use	7,552	7,010
Total current liabilities	59,478	60,163
Operating lease liability - right of use, net of current portion	13,167	17,067
Other non-current liabilities	373	—
Total liabilities	73,018	77,230
Commitments and contingencies (Note 12)		
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; 60,777,558 and 60,383,867 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	61	60
Additional paid-in capital	1,767,811	1,732,772
Accumulated deficit	(1,004,429)	(877,437)
Accumulated other comprehensive loss	(409)	(288)
Total stockholders' equity	763,034	855,107
Total liabilities and stockholders' equity	$ 836,052	$ 932,337

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue:				
Milestone	$ —	$ 25,000	$ —	$ 25,000
Cost-sharing, net	2,294	3,678	4,656	6,502
Royalty	25,646	11,074	48,042	12,594
Total revenue (all amounts are with a related party)	27,940	39,752	52,698	44,096
Costs and expenses:				
Research and development	56,130	38,251	113,429	75,917
Selling, general and administrative	35,472	20,414	66,534	38,663
Total costs and expenses	91,602	58,665	179,963	114,580
Loss from operations	(63,662)	(18,913)	(127,265)	(70,484)
Other income, net	149	466	286	1,113
Loss before income taxes	(63,513)	(18,447)	(126,979)	(69,371)
Income tax provision	(8)	(4)	(13)	(20)
Net loss	$ (63,521)	$ (18,451)	$ (126,992)	$ (69,391)
Other comprehensive income (loss):				
Net unrealized holding gains (losses) on short-term and long-term investments during the period, net of tax	8	161	(121)	(106)
Comprehensive loss	$ (63,513)	$ (18,290)	$ (127,113)	$ (69,497)
Net loss per share- basic and diluted	$ (1.05)	$ (0.34)	$ (2.10)	$ (1.29)
Weighted-average number of common shares used in computing net loss per share- basic and diluted	60,724	53,860	60,524	53,610

See accompanying notes to these condensed consolidated financial statements.

Acceleron Pharma Inc.

Condensed Consolidated Statements of Stockholders' Equity

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

(unaudited)

Three and Six Months Ended June 30, 2021

	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2020	60,383,867	$ 60	$ 1,732,772	$ (877,437)	$ (288)	$ 855,107
Stock-based compensation	—	—	15,626	—	—	15,626
Exercise of stock options	149,724	—	5,865	—	—	5,865
Vesting of restricted stock units, net of shares withheld for taxes	84,902		(3,888)	—	—	(3,888)
Issuance of common stock related to ESPP	20,001	—	1,721	—	—	1,721
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	(129)	(129)
Net loss	—	—	—	(63,471)		(63,471)
Balance at March 31, 2021	60,638,494	60	1,752,096	(940,908)	(417)	810,831
Stock-based compensation	—	—	13,479	—	—	13,479
Exercise of stock options	100,450	—	4,055	—	—	4,055
Vesting of restricted stock units, net of shares withheld for taxes	38,614	1	(1,819)	—	—	(1,818)
Unrealized gain on available-for-sale securities	—	—	—		8	8
Net loss	—	—	—	(63,521)	—	(63,521)
Balance at June 30, 2021	60,777,558	$ 61	$ 1,767,811	$ (1,004,429)	$ (409)	$ 763,034

Three and Six Months Ended June 30, 2020

	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2019	53,123,567	$ 53	$ 1,160,807	$ (711,407)	$ 23	$ 449,476
Stock-based compensation	—	—	6,679	—		6,679
Exercise of stock options	295,757	—	8,485	—		8,485
Vesting of restricted stock units, net of shares withheld for taxes	77,949	—	(472)	—		(472)
Issuance of common stock related to ESPP	22,647	—	860	—		860
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	(267)	(267)
Net loss	—	—	—	(50,939)		(50,939)
Balance at March 31, 2020	53,519,920	53	1,176,359	(762,346)	(244)	413,822
Stock-based compensation	—	—	7,140	—	—	7,140
Exercise of stock options	617,441	1	19,609	—	—	19,610
Vesting of restricted stock units, net of shares withheld for taxes	29,351	—	(663)	—	—	(663)
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	161	161
Net loss	—	—	—	(18,451)	—	(18,451)
Balance at June 30, 2020	54,166,712	$ 54	$ 1,202,445	$ (780,797)	$ (83)	$ 421,619

Acceleron Pharma Inc.

Condensed Consolidated Statements of Cash Flows

(amounts in thousands)

(unaudited)

	Six Months Ended June 30,	
	2021	**2020**
Operating Activities		
Net loss	$ (126,992)	$ (69,391)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,062	1,938
Stock-based compensation	29,105	13,819
Other non-cash items	(3,459)	1,563
Changes in assets and liabilities:		
Prepaid expenses and other assets	(49,201)	(9,293)
Collaboration receivables (all amounts are with a related party)	(1,836)	(31,205)
Non-cash lease expense	3,189	2,792
Accounts payable	542	10,334
Accrued expenses	(2,391)	(6,998)
Operating lease obligations	(3,358)	(2,977)
Other changes in operating assets and liabilities	—	17
Net cash used in operating activities	(152,339)	(89,401)
Investing Activities		
Purchases of investments	(381,477)	(58,539)
Proceeds from sales and maturities of investments	195,019	168,385
Purchases of property and equipment	(1,889)	(2,420)
Net cash (used in) provided by investing activities	(188,347)	107,426
Financing Activities		
Net proceeds from exercises and vesting of stock awards, and ESPP contributions	5,933	27,819
Net cash provided by financing activities	5,933	27,819
Net (decrease) increase in cash, cash equivalents and restricted cash	(334,753)	45,844
Cash, cash equivalents and restricted cash at beginning of period	672,549	239,274
Cash, cash equivalents and restricted cash at end of period	$ 337,796	$ 285,118
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Purchase of property and equipment included in accounts payable and accrued expenses	$ 626	$ 352
Capitalized follow-on public offering costs included in accrued expenses	$ —	$ 423
Additions to property and equipment for asset retirement obligation	$ 373	$ —

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 biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat serious and rare diseases. The Company's leadership in the understanding of TGF-beta biology and protein engineering generates innovative compounds that engage the body's ability to regulate cellular growth and repair.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the risk that the Company never achieves profitability or successfully commercializes its products, the need for substantial additional financing, risks 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 and reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the financial statements. As of June 30, 2021, 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, 2020, have not changed, and the unaudited interim condensed financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2020. In the opinion of management, the accompanying interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2021, the results of its operations for the three and six months ended June 30, 2021 and 2020, stockholders' equity for the three and six months ended June 30, 2021 and 2020, and its cash flows for the six months ended June 30, 2021 and 2020.

The accompanying interim condensed consolidated financial statements include the results of operations of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The results for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, 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, 2020, 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, 2020.

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 condensed 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 condensed 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 condensed consolidated financial statements, management used estimates in the following areas, among others: accrued and prepaid clinical expenses, contract manufacturing expense, stock-based compensation expense, revenue recognition, 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.

5. Cash, 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 in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair 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, 2021 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 six months ended June 30, 2021, and 2020.

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 interest and dividends on securities classified as available-for-sale in interest income in the accompanying condensed consolidated statements of operations and comprehensive loss. Accrued interest receivable relating to the Company's available-for-sale securities is presented within prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets, and amounted to $1.8 million and $0.3 million at June 30, 2021 and December 31, 2020, respectively.

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Financial Instruments-Credit Losses*. The new standard requires an estimate of expected credit losses only when the fair value of an available-for-sale debt security is below its amortized cost basis, and credit losses are limited to the amount by which the security's amortized cost basis exceeds its fair value. Credit-related impairment is recognized as an allowance for credit losses on the balance sheet with a corresponding adjustment to earnings.

The standard additionally requires an investor to determine whether a decline in the fair value below the amortized cost basis of an available-for-sale debt security is due to credit-related factors or noncredit-related factors. Any impairment that is not credit related is recognized in other comprehensive income, net of applicable taxes. The Company adopted ASU 2016-13 effective January 1, 2020, with no material impact on its consolidated financial statements and related disclosures.

The following is a summary of available-for-sale securities with unrealized losses for less than 12 months as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021		December 31, 2020	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate obligations	$ 239,234	$ (160)	$ 54,724	$ (13)
U.S. Treasury securities	12,011	(1)	72,289	(7)
Mortgage and other asset backed securities	—	—	4,998	(2)
Total available-for sale securities in an unrealized loss position	$ 251,245	$ (161)	$ 132,012	$ (22)

At June 30, 2021, our security portfolio consisted of 122 securities related to investments in debt securities available-for-sale, of which 83 securities were in an unrealized loss position. There were no securities in an unrealized loss position for greater than 12 months as of June 30, 2021. The unrealized losses on the Company's available-for-sale securities were caused by central bank and market interest rate decreases on securities purchased at a premium. The contractual terms of these investments do not permit the issuer to settle the securities at a price less than the amortized cost bases of the investments. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases. The Company did not record an allowance for credit losses as of June 30, 2021.

The following is a summary of cash, cash equivalents and available-for-sale securities as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	$ 336,199	$ —	$ —	$ 336,199
Available-for-sale securities:				
Corporate obligations	324,348	21	(160)	324,209
U.S. Treasury securities	52,132	5	(1)	52,136
Total available-for-sale securities (1)	$ 376,480	$ 26	$ (161)	$ 376,345
Total cash, cash equivalents and available-for-sale securities	$ 712,679	$ 26	$ (161)	$ 712,544

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	$ 670,952	$ —	$ —	$ 670,952
Available-for-sale securities:				
Corporate obligations	45,989	5	(13)	45,981
U.S. Treasury securities	135,315	3	(7)	135,311
Certificates of deposit	245	1	—	246
Mortgage and other asset backed securities	5,000	—	(2)	4,998
Total available-for-sale securities (1)	$ 186,549	$ 9	$ (22)	$ 186,536
Total cash, cash equivalents and available-for-sale securities	$ 857,501	$ 9	$ (22)	$ 857,488

(1) All available-for-sale securities mature within two and three years as of June 30, 2021 and December 31, 2020, respectively.

6. Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts presented in the statements of cash flows (in thousands):

	June 30,	
	2021	2020
Cash and cash equivalents	$ 336,199	$ 283,521
Restricted cash	1,597	1,597
Total cash, cash equivalents and restricted cash presented in the statement of cash flows	$ 337,796	$ 285,118

As of June 30, 2021 and December 31, 2020, the Company maintained letters of credit totaling $1.6 million held in the form of certificates of deposit and money market funds as collateral for the Company's facility lease obligation and its credit cards. Restricted cash is included within other assets in the condensed consolidated balance sheet.

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 are primarily 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 collaboration partner. 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 allowance for credit losses has been recorded for the Company's collaboration receivables as of June 30, 2021 and December 31, 2020.

8. Fair Value Measurements

The following tables set forth the Company's financial instruments carried at fair value using the lowest level of input that is significant to each financial instrument as of June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 288,658	$ —	$ —	$ 288,658
Corporate obligations	—	324,209	—	324,209
U.S. Treasury securities	—	52,136	—	52,136
Total assets	$ 288,658	$ 376,345	$ —	$ 665,003

	December 31, 2020			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 266,562	$ —	$ —	$ 266,562
Corporate obligations	—	60,982	—	60,982
U.S. Treasury securities	—	215,310	—	215,310
Certificates of deposit	—	246	—	246
Mortgage and other asset backed securities	—	4,998	—	4,998
Total assets	$ 266,562	$ 281,536	$ —	$ 548,098

The money market funds noted above are included in cash and cash equivalents in the accompanying condensed consolidated 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, 2021 or the year ended December 31, 2020. Items measured at fair value on a recurring basis include short-term and long-term investments (Note 5).

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 and Six Months Ended June 30,	
	2021	2020
Outstanding stock options	$ 3,739	$ 3,680
Common stock warrants	—	39
Shares issuable under employee stock purchase plan	9	13
Outstanding restricted stock units (1)	663	532
	$ 4,411	$ 4,264

(1) This balance is comprised of both the restricted stock units and performance-based restricted stock units described in Note 14.

10. Comprehensive Loss

Comprehensive 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. Comprehensive loss consists of net loss and other comprehensive income (loss), which includes certain changes in equity that are excluded from net loss. Comprehensive loss has been disclosed in the accompanying condensed consolidated statements of operations and comprehensive loss. Accumulated other comprehensive income (loss) is presented separately on the condensed consolidated balance sheets and consists entirely of unrealized holdings gains or losses on investments as of June 30, 2021 and December 31, 2020.

11. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Prepaid clinical trial expenses	$ 58,901	$ 7,930
Accrued interest	1,782	345
Other prepaid and current assets	5,803	8,990
Total prepaid expenses and other current assets	$ 66,486	$ 17,265

12. Commitments and Contingencies

Operating Leases

The Company leases its facilities under non-cancelable operating leases that expire at various dates from September 2023 through May 2026. All of the Company's leases contain escalating rent clauses, which require higher rent payments in future years. See Note 2 and Note 14 in our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information regarding the Company's operating leases.

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 and six months ended June 30, 2021, 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, 2021 and December 31, 2020, or royalties on future sales of specified products. See Note 13 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.

13. Significant Agreements

BMS (Bristol Myers Squibb Company)

Overview

On February 20, 2008, the Company entered into an agreement with Celgene, which was acquired by BMS in November 2019 and is now referred to herein as BMS, relating to sotatercept (the Original Sotatercept Agreement), which was amended on August 2, 2011 (as amended, the Amended Sotatercept Agreement). The Company further amended and restated the Original Sotatercept Agreement in its entirety on September 18, 2017, and clarified certain responsibilities of the Company and BMS in a letter agreement to the Restated Sotatercept Agreement on March 10, 2020 (collectively, the Restated Sotatercept Agreement). On August 2, 2011, the Company entered into a second agreement with BMS for REBLOZYL® (luspatercept-aamt) (the REBLOZYL Agreement, formerly the Luspatercept Agreement).

Since December 31, 2020, there have been no material changes to the key terms of the above agreements. For further information on the terms of the agreements, please see the notes to the consolidated financial statements included in the Company's Form 10-K for the year ended December 31, 2020.

Accounting Analysis

Upon adoption of ASC 606, all of the Company's performance obligations pursuant to its arrangements with BMS were completed and all remaining potential milestone payments were fully constrained as they related to future regulatory events that were outside of the Company's control, and therefore the risk of significant reversal in the amount of cumulative revenue had not been resolved. As of June 30, 2021, the last remaining regulatory milestone payment for REBLOZYL would be $20.0 million and would result from approval by a regulatory authority in Asia (as defined in the REBLOZYL Agreement) of a Biologics License Application (BLA) or equivalent for luspatercept-aamt in either myelodysplastic syndromes or beta-thalassemia. In accordance with the Company's accounting policy regarding revenue recognition as described in Note 2 to its Annual Report on Form 10-K, the revenue associated with this milestone will be recognized once it is probable that the application is approved by the regulatory authority. Milestone payments that are not within the control of the Company or the licensee are not considered probable of being achieved until those approvals are received. The approval of the application is not within the control of the Company or the licensee, and therefore, as of June 30, 2021, the Company cannot determine if it is probable that a regulatory agency will approve the applications.

During the three and six months ended June 30, 2021 and 2020, the Company recognized milestone, cost-sharing, and royalty revenue pursuant to the BMS arrangements, as presented on the condensed consolidated statements of operations and comprehensive loss. Through June 30, 2021, under all BMS arrangements, the Company has received net cost-share payments, milestones, and royalties of $307.4 million and $45.1 million for REBLOZYL and sotatercept, respectively.

Other Agreements

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. The Company agreed to pay specified development milestone payments totaling up to $2.0 million for sotatercept and $0.7 million for REBLOZYL. 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 royalties ranging from 1.0%-3.5% of net sales on any products developed under the licenses. During the three months ended June 30, 2021 and 2020, the Company expensed zero and $1.5 million, respectively, of milestones and fees. During the six months ended June 30, 2021 and 2020, the Company expensed zero and $1.8 million, respectively, of milestones and fees. Milestones and fees associated with development related activities are recorded as research and development expense. During the three months ended June 30, 2021 and 2020, the Company expensed $1.3 million and $0.6 million, respectively, and during the six months ended June 30, 2021 and 2020, the Company expensed $2.5 million and $0.7 million, respectively, of royalties. Costs related to royalties on sales of commercial products are recorded as selling, general and administrative expense.

In May 2014, the Company executed a collaboration agreement with a research technology company, and such collaboration agreement was amended and restated in March 2019. The Company paid an upfront research fee of $0.3 million upon execution of the original agreement. The Company also received an option to obtain a commercial license to the molecules developed during the collaboration. During the three and six months ended June 30, 2021 and 2020, the Company expensed zero and $0.5 million, respectively, of milestones and fees, which is recorded as research and development expense.

In December 2019, the Company executed a license and collaboration agreement with Fulcrum Therapeutics to identify small molecules designed to modulate specific pathways associated with a targeted indication within the pulmonary disease space. The Company paid an upfront research fee of $10.0 million upon execution of this agreement, which was expensed to research and development. The Company also agreed to pay specified research, development and commercial milestone payments of up to $295.0 million for a first product commercialized and up to a maximum of $143.5 million in additional milestone payments for all subsequent products commercialized. Fulcrum will additionally receive tiered royalty payments in the mid-single-digit to low double-digit range on net sales, as well as reimbursement for relevant research and development costs. During the three months ended June 30, 2021 and 2020, the Company expensed $0.6 million and $0.8 million, respectively, and during the six months ended June 30, 2021 and 2020, the Company expensed $1.1 million and $1.1 million, respectively, of milestones and fees, which is recorded as research and development expense.

14. Stock-Based Compensation

During the quarter ended March 31, 2021, the Company updated the equity award agreements with respect to the 2013 Equity Incentive Plan (the 2013 Plan) to enhance the vesting terms for retirement eligible employees and directors for awards granted in 2021 and future awards. Where awards are granted with non-substantive vesting periods (for instance, where all or a portion of the award continues to vest upon retirement eligibility), the Company recognizes expense based on the period from the grant date to the date the employee becomes retirement eligible.

The Company recognized stock-based compensation expense related to the 2003 Stock Option and Restricted Stock Plan (the 2003 Plan), the 2013 Plan, and the 2013 Employee Stock Purchase Plan (the 2013 ESPP) in the condensed consolidated statements of operations and comprehensive loss during the three and six months ended June 30, 2021 and 2020, respectively, as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 5,876	$ 3,259	$ 14,032	$ 6,400
Selling, general and administrative	7,603	3,881	15,073	7,419
	$ 13,479	$ 7,140	$ 29,105	$ 13,819

Stock Options

The following table summarizes the stock option activity under the Company's stock option plans during the six months ended June 30, 2021 (in thousands, except per share amounts and years):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (1)
Outstanding at December 31, 2020	3,378	$ 49.78	7.35	$ 264,046
Granted	672	$ 118.71		
Exercised	(250)	$ 39.77		
Canceled or forfeited	(61)	$ 77.50		
Outstanding at June 30, 2021	3,739	$ 62.39	7.43	$ 236,601
Exercisable at June 30, 2021	1,863	$ 42.57	6.21	$ 154,466

(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, 2021.

The aggregate intrinsic value of options exercised during the six months ended June 30, 2021 was $22.3 million.

As of June 30, 2021, there was approximately $70.0 million of unrecognized compensation expense related to unvested stock options that is expected to be recognized over a remaining weighted-average period of 2.61 years.

Restricted Stock Units

The following table summarizes the restricted stock unit (RSU) activity under the 2013 Plan during the six months ended June 30, 2021 (in thousands, except per share amounts):

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at December 31, 2020	494	$ 59.16
Granted	197	$ 117.45
Vested	(169)	$ 46.05
Forfeited	(15)	$ 77.45
Unvested balance at June 30, 2021	507	$ 85.65

As of June 30, 2021, there was approximately $33.1 million of unrecognized compensation expense related to RSUs that is expected to be recognized over a remaining weighted-average period of 1.86 years.

Performance-Based Restricted Stock Units

On January 22, 2020, the Company granted performance-based restricted stock units (PSU) whereby vesting depends upon the occurrence of certain milestone events by December 31, 2022 (the 2020 PSUs). When achievement of a milestone event becomes probable, compensation cost will be recognized from the grant date over the requisite service period and a cumulative catch-up adjustment will be recorded to reflect the portion of the employees' requisite service that has been provided to date. During the three months ended June 30, 2021, stock-based compensation expense of $1.9 million related to the 2020 PSUs was recognized for one of the milestone events deemed probable of achievement. The expense associated with these PSUs will continue to be recognized through December 31, 2022. For the remaining two milestone events which were not deemed probable of achievement, no stock-based compensation expense was recognized.

On January 29, 2021, the Company granted performance-based restricted stock units (PSU) whereby vesting depends upon the occurrence of certain milestone events by December 31, 2023 (the 2021 PSUs). When achievement of a milestone event becomes probable, compensation cost will be recognized from the grant date over the requisite service period and a cumulative catch-up adjustment will be recorded to reflect the portion of the employees' requisite service that has been provided to date. As of June 30, 2021, none of the milestone events related to the 2021 PSUs had been deemed probable of being achieved.

The following table summarizes PSU activity under the 2013 Plan during the six months ended June 30, 2021 (in thousands, except per share amounts):

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at December 31, 2020	75	$ 52.99
Granted (1)	83	$ 115.53
Vested	—	$ —
Forfeited	(2)	$ 52.99
Unvested balance at June 30, 2021	156	$ 86.01

(1) Pursuant to the terms of the awards granted, the actual number of awards earned could range between 0% and 200% of the number of awards granted.

As of June 30, 2021, there was approximately $11.5 million of related unrecognized compensation cost. Depending on the actual number of milestone events achieved, the actual expense recognized could range between 0% and 200% of the total target value awarded on the grant date.

15. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

16. Related Party Transactions

BMS

BMS owned 10.7% and 10.8% of the Company's fully diluted equity as of June 30, 2021 and December 31, 2020, respectively. Refer to Note 13 for additional information regarding this collaboration arrangement.

During the three and six months ended June 30, 2021 and 2020, all revenue recognized by the Company was recognized under the BMS collaboration arrangement.

17. 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.

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, 2020.

Certain matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. 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," "vision," "will," "would," 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:

- *the impact on our business of the COVID-19 pandemic and the government's efforts to contain it;*
- *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 sotatercept in pulmonary hypertension, ACE-1334, and our other potential therapeutic candidates;*
- *our and Bristol Myers Squibb's, or BMS's, plans to develop and commercialize REBLOZYL® (luspatercept-aamt) and sotatercept outside of pulmonary hypertension;*
- *the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnership arrangements;*
- *the timing of anticipated milestone payments under our collaboration agreements with BMS;*
- *the timing of, and our and/or BMS'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 manufacturing capabilities and strategy;*
- *our plans for commercialization and marketing;*
- *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 change 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, 2020 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.

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of 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. 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 generate innovative therapeutic candidates, all of which encompass novel potential first-in-class mechanisms of action. If successful, these candidates could have the potential to significantly improve clinical outcomes for patients across these areas of high, unmet need.

We focus and prioritize our commercialization, research and development activities within two key therapeutic areas: pulmonary and hematology.

Pulmonary

We are actively developing our lead pulmonary program, sotatercept, for the treatment of patients with pulmonary arterial hypertension, or PAH. Sotatercept is generally partnered with Bristol Myers Squibb, or BMS, (which acquired Celgene Corporation in November 2019), but we retain the exclusive rights to fund, develop, and lead the global commercialization of sotatercept in pulmonary hypertension, which we refer to as the PH field, and that includes PAH. PAH is a rare and chronic, rapidly progressing disorder characterized by the constriction of small pulmonary arteries, resulting in abnormally high blood pressure in the pulmonary arteries.

In June 2020, we presented results of the PULSAR Phase 2 trial of sotatercept in patients with PAH on stable background PAH-specific therapies during the "Breaking News: Clinical Trials in Pulmonary Medicine" session of the American Thoracic Society, or ATS, 2020 Virtual Conference. Study investigators reported that the trial met its primary endpoint, pulmonary vascular resistance, and its key secondary endpoint, six-minute walk distance, and showed concordance of results across multiple additional endpoints and regardless of baseline characteristics. Sotatercept was generally well tolerated in the trial and adverse events observed in the study were generally consistent with previously published data on sotatercept in clinical trials in other patient populations. We presented additional cardiac and pulmonary function data at the virtual 2020 American Heart Association Scientific Sessions in November 2020 showing improvement in right ventricular-pulmonary arterial (RV-PA) coupling, which represents the match between the output of the RV and the resistance of the pulmonary vasculature, as well as improvement in RV function. In May 2021, we presented interim results from the ongoing 18-month open-label extension of the PULSAR trial at the ATS 2021 International Conference showing consistent or improved patient responses in multiple efficacy endpoints when treated with sotatercept for up to 48 weeks. We initiated our registrational Phase 3 trial, the STELLAR trial, in patients with PAH at the end of 2020, and start-up activities are underway for the early intervention Phase 3 HYPERION trial in patients with PAH and the later intervention Phase 3 ZENITH trial in World Health Organization (WHO) functional class IV PAH patients, each of which we plan to initiate in the second half of 2021. In addition, we plan to initiate the Phase 2 CADENCE trial in patients with pulmonary hypertension with left heart disease in the second half of 2021.

We have completed enrollment in an exploratory study called SPECTRA to provide us with greater understanding of sotatercept's potential impact on PAH. We presented preliminary interim results in November 2020 at the virtual 2020 American Heart Association Scientific Sessions, and we presented additional preliminary interim results at the ATS 2021 International Conference, in each case showing improvements in multiple hemodynamic measures in the first 10 patients evaluated among the total of 21 trial participants. We also previously announced that the U.S. Food and Drug Administration, or FDA, has granted Breakthrough Therapy designation to sotatercept for the treatment of patients with PAH, and that the European Medicines Agency, or EMA, has granted Priority Medicines, or PRIME, designation to sotatercept for the treatment of patients with PAH. In December 2020, the European Commission granted Orphan Drug designation to sotatercept for the treatment of patients with PAH.

If sotatercept is approved and commercialized to treat PAH, then we will recognize revenue from global net sales and owe BMS a royalty in the low 20% range.

In addition to sotatercept, we are currently advancing our second pulmonary therapeutic candidate, ACE-1334. ACE-1334 is a wholly owned TGF-beta superfamily-based ligand trap designed to bind and inhibit TGF-beta 1 and 3 ligands but not TGF-beta 2. We recently completed an ascending-dose Phase 1 clinical trial in healthy volunteers, and the FDA has granted Fast Track designation to ACE-1334 in patients with systemic sclerosis-associated interstitial lung disease, or SSc-ILD, as well as Orphan Drug designation for the treatment of systemic sclerosis. SSc-ILD is a rare, progressive, autoimmune connective tissue disorder characterized by immune dysregulation. We intend to initiate a Phase 1b/Phase 2 clinical trial with ACE-1334 in patients with SSc-ILD by the end of 2021.

Hematology

Our first commercial product, REBLOZYL® (luspatercept-aamt), is a first-in-class erythroid maturation agent designed to promote red blood cell, or RBC, production through a novel mechanism, and is partnered with BMS. REBLOZYL is currently approved to treat certain adult patients with beta-thalassemia or MDS in the United States, European Union and Canada, as further described in the "Business" section in our Annual Report on Form 10-K for the year ended December 31, 2020.

For additional patient populations, BMS is currently conducting a Phase 2 clinical trial with luspatercept-aamt in non-transfusion-dependent beta-thalassemia patients, referred to as the BEYOND trial, and a Phase 3 clinical trial, the COMMANDS trial, in first-line, lower-risk MDS patients. In June 2021, we and BMS announced the first results from the BEYOND trial showing that luspatercept-aamt plus best supportive care improved anemia in 77% of patients compared to placebo, and luspatercept-aamt was generally well tolerated. Topline results from the COMMANDS trial are expected in or after 2022. In myelofibrosis, BMS is conducting a Phase 2 clinical trial with luspatercept-aamt in patients with myelofibrosis-associated anemia, and has initiated the Phase 3 INDEPENDENCE study in patients with myelofibrosis-associated anemia who are being treated with JAK inhibitor therapy and require RBC transfusions.

We believe that there is a global annual peak sales opportunity for REBLOZYL in excess of $4 billion for all currently approved indications and those in development, including future clinical development expansion.

BMS is responsible for paying 100% of the development costs for all clinical trials for luspatercept-aamt. We may receive a maximum of $100.0 million for remaining potential regulatory and commercial milestone payments. We have a co-promotion right in North America and our commercialization costs provided in the commercialization plan and budget approved by the Joint Commercialization Committee, or JCC, are entirely funded by BMS. Activities that we elect to conduct outside of the approved development or commercialization budgets to support REBLOZYL are at our own expense. We are eligible to receive tiered royalty payments from BMS on net sales of REBLOZYL in the low-to-mid 20% range.

Funding and Expense

As of June 30, 2021, our operations have been funded primarily by $105.1 million in equity investments from venture investors, $1.3 billion from public investors, $164.1 million in equity investments from our collaboration partners and $482.6 million in upfront payments, milestones, royalties, and net research and development payments from our collaboration partners.

We expect our expenses will increase substantially in connection with our ongoing activities, if and as we:

- conduct clinical trials for sotatercept in the PH field or any future therapeutic candidates;
- prepare for the potential launch and commercialization of sotatercept in the PH field;
- 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, and potentially for commercialization;
- establish and maintain a sales, marketing and distribution infrastructure to commercialize any products for which we have or may obtain regulatory approval;
- acquire or in-license other therapeutic candidates and patents;
- seek regulatory approval for our therapeutic candidates; and
- attract and retain skilled personnel.

If we obtain regulatory approval for sotatercept in the PH field, 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 royalty revenue from the sale of our first and only commercial product, REBLOZYL, and potentially from the sale of equity, debt financings or other sources, including potential additional collaborations. However, we may not generate sufficient royalty revenue and 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 generate significant revenue or 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.

Financial Operations Overview

Impact of COVID-19 on our Business

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization (WHO) in March 2020 and has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. As of June 30, 2021, we have not experienced material financial, development, or supply chain impacts directly related to the pandemic, but we may experience disruptions in our ongoing and planned sotatercept and ACE-1334 clinical trials. We have experienced disruptions in our commercialization efforts for REBLOZYL with regard to customer engagement and in-person promotion. New patient visits for MDS patients in general have also decreased as compared to pre-COVID levels. Although some restrictions on our in-person promotion efforts were reduced during the quarter ended June 30, 2021, these restrictions have begun to return recently due to an increase in COVID cases and related hospitalizations attributed to the spread of the delta variant. In addition, as various geographies in the United States and worldwide adapt to surging COVID-19 infections from the delta variant or other new variants, we may experience additional setbacks to our operations, including our clinical trial initiations and enrollment, that could have a material impact on our business.

For a discussion of the risks presented by the COVID-19 pandemic to our results, see Risk Factors in Part I, Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Revenue

Collaboration Revenue

Our revenue to date has been predominantly derived from collaboration revenue, which includes license and milestone revenue, cost-sharing revenue, and royalties, 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 co-promotion activities under our collaboration agreements. Cost-sharing revenue is recognized in the period that the related activities are performed. Royalty revenue is recognized in the period that the related sales occur.

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, including costs incurred under agreements with contract manufacturing organizations, or CMOs, 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 beyond the initial approvals of REBLOZYL. The duration, costs and timing of clinical trials and development of 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 FDA, 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 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, 2021, we have incurred $1.1 billion 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 our clinical programs. Research and development expenses associated with luspatercept-aamt, and, outside of the PH field, sotatercept, are generally reimbursed 100% by BMS. These reimbursements are recorded as cost-sharing revenue. We are expensing the costs of clinical trials for sotatercept and ACE-1334. With respect to the luspatercept-aamt clinical trials directly conducted by BMS, 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 and CMOs. 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 by CMOs, 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, except for luspatercept-aamt costs for the purposes of billing BMS. Our external research and development expenses during the three and six months ended June 30, 2021 and 2020 are as follows (certain prior year amounts have been reclassified to conform with current year presentation):

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Sotatercept (1)	$ 17,655	$ 8,744	$ 38,628	$ 17,724
ACE-083 (2)	14	2,338	171	6,524
ACE-1334 (3)	1,746	1,620	2,936	3,380
Total direct research and development expenses	19,415	12,702	41,735	27,628
Other expenses (4)	36,715	25,549	71,694	48,289
Total research and development expenses	$ 56,130	$ 38,251	$ 113,429	$ 75,917

(1) These expenses are associated with our development of sotatercept in PAH.

(2) Development of ACE-083 was discontinued. All remaining material expenses were incurred as of the end of 2020.

(3) These expenses are associated with our development of ACE-1334 in SSc-ILD.

(4) Other expenses include employee and unallocated contractor-related expenses, facility expenses, lab supplies, and miscellaneous expenses, including expenses associated with preclinical and other development programs.

Selling, General and Administrative Expenses

Selling, 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, commercial, operational, finance and human resource functions. Selling, general and administrative expenses also include directors' fees, professional fees for accounting and legal services, other miscellaneous costs associated with supporting our sales, marketing and investor relations activities, and allocated facilities, depreciation, and other expenses, such as rent and maintenance of facilities, insurance and other supplies.

We anticipate that our selling, 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 Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash, cash equivalents and investments. Prior to 2021, other income (expense), net also consists of the re-measurement gain or loss associated with the change in the fair value of our common stock warrant liabilities.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed 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 condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition and accrued and prepaid clinical expenses. 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.

During the three and six months ended June 30, 2021, there have been no material changes to our critical accounting policies as reported in our Annual Report on the Form 10-K for the year ended December 31, 2020. 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, 2020.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

(in thousands)	Three Months Ended June 30, 2021	2020	Increase (Decrease) $	%
Revenue:				
Collaboration revenue:				
Milestone	$ —	$ 25,000	$ (25,000)	(100)%
Cost-sharing, net	2,294	3,678	(1,384)	(38)%
Royalty	25,646	11,074	14,572	132 %
Total revenue (all amounts are with a related party)	27,940	39,752	(11,812)	(30)%
Costs and expenses:				
Research and development	56,130	38,251	17,879	47 %
Selling, general and administrative	35,472	20,414	15,058	74 %
Total costs and expenses	91,602	58,665	32,937	56 %
Loss from operations	(63,662)	(18,913)	(44,749)	237 %
Other income, net	149	466	(317)	(68)%
Loss before income taxes	(63,513)	(18,447)	(45,066)	244 %
Income tax provision	(8)	(4)	(4)	100 %
Net loss	$ (63,521)	$ (18,451)	$ (45,070)	244 %

Revenue. We recognized revenue of $27.9 million in the three months ended June 30, 2021, compared to $39.8 million in the same period in 2020. All of the revenue in both periods was derived from the BMS agreements. This $11.8 million decrease is primarily related to a decrease of $25.0 million in license and milestone revenue, partially offset by increased royalty revenue from REBLOZYL sales recognized in 2021 of $14.6 million.

Research and Development Expenses. Research and development expenses were $56.1 million in the three months ended June 30, 2021, compared to $38.3 million in the same period in 2020. This $17.9 million increase is primarily related to growth in order to support our wholly-owned therapeutic candidates and preclinical programs and includes:

- an increase in external clinical trial expense of $12.0 million primarily related to increased clinical activities for the sotatercept clinical trials;
- an increase in personnel and facilities-related expense of $9.5 million related to increased headcount to support our growth; and
- an increase in miscellaneous research expense of $0.8 million; offset by
- a decrease in contract manufacturing, drug supply, and development expenses of $4.1 million related to our ongoing clinical and preclinical programs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $35.5 million in the three months ended June 30, 2021, compared to $20.4 million in the same period in 2020. The $15.1 million increase is primarily due to the following factors:

- an increase in personnel and facilities-related expense of $8.7 million related to increased headcount to support our growth; and
- an increase in consulting and other miscellaneous expenses of $5.9 million primarily related to the preparation for the potential future commercial launch of sotatercept and other activities related to the execution of our global strategy.

Comparison of the Six Months Ended June 30, 2021 and 2020

(in thousands)	Six Months Ended June 30, 2021	2020	Increase (Decrease) $	%
Revenue:				
Collaboration revenue:				
Milestone	$ —	$ 25,000	$ (25,000)	(100)%
Cost-sharing, net	4,656	6,502	(1,846)	(28)%
Royalty	48,042	12,594	35,448	281 %
Total revenue (all amounts are with a related party)	52,698	44,096	8,602	20 %
Costs and expenses:				
Research and development	113,429	75,917	37,512	49 %
Selling, general and administrative	66,534	38,663	27,871	72 %
Total costs and expenses	179,963	114,580	65,383	57 %
Loss from operations	(127,265)	(70,484)	(56,781)	81 %
Other income, net	286	1,113	(827)	(74)%
Loss before income taxes	(126,979)	(69,371)	(57,608)	83 %
Income tax provision	(13)	(20)	7	(35)%
Net loss	$ (126,992)	$ (69,391)	$ (57,601)	83 %

Revenue. We recognized revenue of $52.7 million in the six months ended June 30, 2021, compared to $44.1 million in the same period in 2020. All of the revenue in both periods was derived from the BMS agreements. This $8.6 million increase is primarily related to increased royalty revenue from REBLOZYL sales recognized in 2021 of $35.4 million, partially offset by decreased license and milestone revenue of $25.0 million.

Research and Development Expenses. Research and development expenses were $113.4 million in the six months ended June 30, 2021, compared to $75.9 million in the same period in 2020. This $37.5 million increase is primarily related to growth in order to support our wholly-owned therapeutic candidates and preclinical programs and includes:

- an increase in personnel and facilities-related expense of $19.1 million related to increased headcount to support our growth;
- an increase in external clinical trial expense of $18.8 million related to increased clinical activities for the sotatercept clinical trials; and
- an increase in miscellaneous research expense of $2.1 million; offset by
- a decrease in contract manufacturing, drug supply, and development expenses of $2.0 million related to our ongoing clinical and preclinical programs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $66.5 million in the six months ended June 30, 2021, compared to $38.7 million in the same period in 2020. The $27.9 million increase is primarily due to the following factors:

- an increase in personnel and facilities-related expense of $15.8 million related to increased headcount to support our growth; and
- an increase in consulting and other miscellaneous expenses of $11.9 million primarily related to the preparation for the potential future commercial launch of sotatercept and other activities related to the execution of our global strategy.

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, 2021, we had an accumulated deficit of $1.0 billion. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we may 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, 2021, our operations have been primarily funded by $105.1 million in equity investments from venture investors, $1.3 billion from public investors, $164.1 million in equity investments from our collaboration partners, and $482.6 million in upfront payments, milestones, royalties, and net research and development payments from our collaboration partners.

As of June 30, 2021, we had $712.5 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.

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,	
(in thousands)	**2021**	**2020**
Net cash (used in) provided by:		
Operating activities	$ (152,339)	$ (89,401)
Investing activities	(188,347)	107,426
Financing activities	5,933	27,819
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (334,753)	$ 45,844

Operating Activities

Net cash used in operating activities was $152.3 million for the six months ended June 30, 2021, compared to $89.4 million during the same period in 2020. Significant factors in this $62.9 million increase include:

- an increase in net loss of $57.6 million primarily due to an increase in operating expenses related to increased headcount and facilities, external expenses for contract manufacturing, prepayment of phase 3 clinical trial activities and the related expense, consulting, and other external expenses to support our wholly-owned therapeutic programs, as well as expenses for commercial activities for REBLOZYL, offset by an increase in royalty revenue associated with sales of REBLOZYL;
- a net increase in operating assets and liabilities of $15.7 million, consisting primarily of an increase in prepaid expenses and other assets of $39.9 million; offset by a net decrease in collaboration receivables and accounts payable of $29.4 million and $9.8 million, respectively; and
- a net increase in other non-cash expenses of $10.3 million, largely related to an increase in stock-based compensation expense of 15.3 million, and offset by a net decrease in amortization and accretion of premiums and discounts on available-for-sale securities of 3.4 million.

Investing Activities

Net cash used in investing activities was $188.3 million for the six months ended June 30, 2021, compared to net cash provided by investing activities of $107.4 million during the same period in 2020. Net cash used and provided by investing activities primarily consisted of the following amounts relating to activity within our investment portfolio:

- for the six months ended June 30, 2021, purchases of investments of $186.5 million net of maturities due to the execution of our investment strategy in accordance with our policy as we invest the money raised in our July 2020 public offering in marketable securities; and
- for the six months ended June 30, 2020, net proceeds from sales and maturities of investments of $109.8 million in connection with managing our investment portfolio to meet our projected cash requirements.

Financing Activities

Net cash provided by financing activities was $5.9 million for the six months ended June 30, 2021, compared to $27.8 million during the same period in 2020. Net cash provided by financing activities consisted primarily of the following:

- for the six months ended June 30, 2021, $5.9 million in cash proceeds from the exercise of stock options and the issuance of common stock related to the employee stock purchase plan; and
- for the six months ended June 30, 2020, $27.8 million in cash proceeds from the exercise of stock options and the issuance of common stock related to the employee stock purchase plan.

Operating Capital Requirements

To date, we have only generated limited revenue from royalties on the sale of our first and only commercial product, REBLOZYL, since receiving our first regulatory approval from the FDA in November 2019. We expect our expenses to increase and to incur losses as we continue the development of, and seek regulatory approvals for, sotatercept in the PH field and any future therapeutic candidates, and as we begin to commercialize any approved products. We are subject to all of the risks inherent 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.

Based on our current operating plan and projections, we believe that our current cash, cash equivalents and investments, along with the expected royalty revenue from REBLOZYL sales, will be sufficient to fund our projected operating requirements for the foreseeable future.

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 generate sufficient revenue or 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 agreements with BMS;
- the amount of royalties we receive on sales of REBLOZYL;
- 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, including potential new facilities;

- 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 costs of preparing for the potential launch and commercialization of sotatercept or our other 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 or wholly-owned intellectual property.

Net Operating Loss (NOL) Carryforwards

We had net deferred tax assets of approximately $282.2 million as of December 31, 2020, 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, research and development tax credit carryforwards, and deferred revenue, accruals and other temporary differences. As of December 31, 2020, we had federal NOL carryforwards of approximately $871.4 million and state NOL carryforwards of $788.3 million available to reduce future taxable income, if any. Of these federal and state NOL carryforwards, $438.0 million and $787.7 million, respectively, will expire at various times through 2040. The federal NOL of $433.4 million and state NOL of $0.6 million generated beginning in 2018 can be carried forward indefinitely. In general, if we experience a greater than 50% 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, 2020.

Contractual Obligations and Commitments

During the three months ended June 30, 2021, 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, 2020.

Recent Accounting Pronouncements

For a summary of recently issued accounting pronouncements applicable to the Company refer to Note 2, "Summary of Significant Accounting Policies" in the Notes to our audited Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2020.

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, 2021 and December 31, 2020, we had cash, cash equivalents and investments of $712.5 million and $857.5 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. 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 impact 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 Securities and Exchange Commission'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, 2021, 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 Securities and Exchange Commission'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, 2021, 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, 2021, 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, 2020.

Item 6. Exhibits

Exhibit Number	Description of Exhibit
10.1+	Collaboration, License and Option Agreement between Acceleron Pharma Inc. and Celgene Corporation, dated as of August 2, 2011
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	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

\+ Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

* This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

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 5, 2021

By: /s/ HABIB J. DABLE
Habib J. Dable
Chief Executive Officer and President

Date: August 5, 2021

By: /s/ KEVIN F. MCLAUGHLIN
Kevin F. McLaughlin
Senior Vice President, Chief Financial Officer and Treasurer

EXHIBIT 10.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

COLLABORATION, LICENSE AND OPTION AGREEMENT

by and between

ACCELERON PHARMA, INC.

and

CELGENE CORPORATION

August 2, 2011

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COLLABORATION, LICENSE AND OPTION AGREEMENT

This Collaboration, License and Option Agreement (this "**Agreement**") dated the 2nd day of August, 2011 (the "**Effective Date**") is 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**."

INTRODUCTION

WHEREAS, the Parties entered into a Collaboration, License and Option Agreement on February 20, 2008 (the "**Original Agreement**"), pursuant to which the Parties are collaborating 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 owns or otherwise controls certain intellectual property relating to ACE-536 (as defined below), including compositions and methods of treatment;

WHEREAS, Celgene is in the business of discovering, developing and commercializing innovative therapies;

WHEREAS, Acceleron and Celgene are interested in collaborating, on the terms and conditions set forth herein, in the investigation and development of ACE-536 in the Field (as defined below); 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 for the treatment of anemia 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 Article 1:

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; provided, however, 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, Phase 2 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 the Territory.

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; provided, however, that Acceleron Improvements shall not include any Improvement that is a Celgene 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 or ligands 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 or ligands are included in the Acceleron Know-How.

1.5 "**Acceleron Patent Rights**" means (a) the United States and foreign Patent Rights listed in Schedule 1.5 and, if any, the Option Patent Rights, (b) any Patent Rights arising from those Patent Rights 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(d)); 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 each case 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 Phase 2 Clinical Trials**" means, subject to Section 2.1.1, (a) the first Phase 2 Clinical Trial for ACE-536 in a myelodysplastic syndrome and (b) the first Phase 2 Clinical Trial for ACE-536 in the second Initial Development Disease selected by the Joint Development Committee for ACE-536, in each case, that is conducted for the purpose of obtaining Regulatory Approval in North America or Europe.

1.7 "**Acceleron Technology**" means Acceleron Patent Rights, Acceleron Know-How, Acceleron Improvements, and Acceleron Collaboration IP.

1.8 "**ACE-011 Agreement**" means the Collaboration, License and Option Agreement entered into by Acceleron and Celgene on February 20, 2008, as amended by the First Amendment dated August 2, 2011 and as further amended from time to time in accordance with its terms.

1.9 "**ACE-536**" means (a) the protein shown in Schedule 1.9, (b) any dimers or multimers of (a), and (c) any nucleic acid encoding a protein of clause (a) or (b) of this Section 1.9.

1.10 "**ActRIIB Compounds**" means (a) any protein or fusion protein containing activin receptor type IIB ("**ActRIIB**") or a fragment of ActRIIB, whether naturally occurring, expressed through recombinant engineering or gene activation, or chemically synthesized (including, but not limited to Fc fusions); or (b) any dimers or multimers of (a); or (c) any nucleic acid encoding the foregoing; provided, however, that "**ActRIIB Compounds**" shall exclude all ActRIIA (as defined in the ACE-011 Agreement) compounds.

1.11 "**Additional Development Disease**" means, with respect to any Licensed Product or Licensed Compound, any disease in the Field which is not an Initial Development Disease with respect to such Licensed Product or Licensed Compound.

1.12 "**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.

1.13 "**Agreement Term**" means the period commencing on the Effective Date and ending upon the termination of this Agreement in accordance with Section 10.1.

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1.14 "**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.

1.15 "**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.

1.16 "**Asia**" means [* * *].

1.17 "**Bankruptcy Code**" means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.18 "**Biosimilar Notice**" means a copy of any application submitted by a Third Party to the FDA under 42 U.S.C. § 262(k) of the PHS Act (or, in the case of a country of the Territory outside the United States, any similar law) for Regulatory Approval of a biological product, which application identifies a Licensed Product as the reference product with respect to such product, and other information that describes the process or processes used to manufacture the biological product.

1.19 "**Business Day**" means a day on which banking institutions in Boston, Massachusetts and Trenton, New Jersey are open for business.

1.20 "**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.

1.21 "**Celgene Development Activities**" means all Development activities (including, if Celgene elects to be responsible pursuant to Section 2.1.2(a), Phase 3 Clinical Trials, any formulation development for Licensed Compounds or Licensed Products taking place after the end of Phase 2 Clinical Trials, and any other Development activities taking place after the end of Phase 2 Clinical Trials) undertaken by Celgene pursuant to this Agreement for the purpose of obtaining Regulatory Approval in the Territory.

1.22 "**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.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

1.23 "**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.

1.24 "**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.

1.25 "**Celgene Technology**" means Celgene Know-How, Celgene Patent Rights, Celgene Improvements, and Celgene Collaboration IP.

1.26 "**Change of Control**" means, with respect to a Party, (a) 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 (b) 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 (c) 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. For the avoidance of doubt, an initial public offering of shares of Acceleron to the public shall not constitute a "Change of Control."

1.27 "**Clinical Hold**" means that (a) the applicable Clinical Trial is put on clinical hold by the applicable Regulatory Authorities and remains on hold for at least one year, (b) the IND or other regulatory approval for the applicable Clinical Trial has been suspended, terminated, or withdrawn by the applicable Regulatory Authorities and remains suspended, terminated, or withdrawn for at least one year, (c) the applicable Clinical Trial has been suspended due to potential toxicity or safety findings or side effects that the Joint Development Committee (with the consent of both Parties) reasonably believes justify suspension of such Clinical Trial, or (d) due to potential toxicity or safety findings or side effects, the independent data monitoring committee recommends termination of such Clinical Trial.

1.28 "**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 EMA 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.

1.29 "**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.

1.30 "**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.

1.31 "**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).

1.32 "**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 EMA 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.

1.33 "**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.

1.34 "**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.

1.35 "**Completion**" means, with respect to a Clinical Trial, the completion of the database lock for the applicable Clinical Trial.

1.36 "**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) was known by the receiving Party or its Affiliates prior to its date of disclosure to the receiving Party; or

(b) 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

(c) 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

(d) is independently developed by or for the receiving Party or its Affiliates without reference to or reliance upon the Confidential Information.

1.37 "**Contract Year**" means each calendar year during the Agreement Term; provided, however, that the first Contract Year shall begin on the Effective Date and end on December 31, 2011. Each Contract Year shall be divided into four (4) "**Contract Quarters**" ending respectively on March 31, June 30, September 30 and December 31.

1.38 "**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.

1.39 "**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.

1.40 "**Developing Party**" means, with respect to any Licensed Product or Licensed Compound, the Party conducting Development activities with respect to such Licensed Compound or Licensed Product pursuant to Section 2.1. The Parties acknowledge that each Party could simultaneously be a Developing Party for a particular Licensed Compound or Licensed Product.

1.41 "**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.

1.42 "**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 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 and implementation of manufacturing technology, from one Party to the other Party or to a Third Party, 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(d);

(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 Section 2.4.2(a).

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.

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1.43 "**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 the Territory, including activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing NDAs in the Territory, 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.

1.44 "**EMA**" means the Regulatory Authority 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.

1.45 "**Europe**" means Switzerland and all countries in which the Development or Commercialization of a Licensed Compound or Licensed Product is regulated by the EMA.

1.46 "**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).

1.47 "**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.

1.48 "**Field**" means:

(a) with respect to any Option Compound deemed a Licensed Compound in accordance with Article 7 (or any Licensed Product that contains such Licensed Compound), (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; and

(b) with respect to ACE-536 or any Licensed Product containing ACE-536, the Use in Anemia; provided that, at such time as the provisions of Section 11.1.2(a) of the Shire Agreement terminate or are modified (to give Acceleron broader rights to develop ACE-536), the "Field" with respect to ACE-536 or any Licensed Product containing ACE-536 shall expand to (i) the treatment, prevention, modulation or diagnosis of any disease, disorder or condition in humans, if the Shire Agreement terminates, or (ii) the broadest scope that is permitted as modified under the Shire Agreement, if the Shire Agreement is modified (provided that the "Field" shall never be less than Use in Anemia).

1.49 "**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 in the Field 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.

1.50 "**FTE Costs**" means, for any Contract Quarter, the FTE Rate multiplied by the number of hours of service spent in such Contract Quarter by employees of Celgene or Acceleron, or their respective Affiliates, working directly on the Development or Commercialization of a Licensed Product.

1.51 "**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).

1.52 "**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).

1.53 "**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.

1.54 "**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 C.F.R. Part 58), FDA guidances, FDA current review and inspection standards and current industry standards.

1.55 "**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.

1.56 "**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.

1.57 "**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.

1.58 "**Initial Development Diseases**" means:

(a) with respect to ACE-536, (i) a disease in the Field with a prevalence of less than 200,000 affected individuals in the United States, which disease is selected by the Joint Development Committee after review of all applicable scientific data regarding ACE-536, and (ii) any myelodysplastic syndrome, and

(b) with respect to any Option Compound that is deemed a Licensed Compound in accordance with Article 7, the initial disease that is selected by the Parties when Celgene exercises its Option with respect to such Option Compound.

1.59 "**Invented**" means the act of invention by inventors, as determined in accordance with U.S. patent laws.

1.60 "**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; provided, however, that Joint Collaboration IP shall not include any Collaboration IP that is Acceleron Collaboration IP or Celgene Collaboration IP.

1.61 "**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.

1.62 "**Joint Patent Rights**" means any Patent Rights resulting from any Joint Improvements or Joint Collaboration IP.

1.63 "**Joint Technology**" means Joint Improvements, Joint Patent Rights, and Joint Collaboration IP.

1.64 "**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.

1.65 "**Licensed Compound**" means (a) ACE-536, and (b) effective upon the dates and pursuant to the terms set forth in Article 7, (i) any applicable Option Compound, (ii) any dimers or multimers of (i), and (iii) any nucleic acid encoding a protein of (i) or (ii).

1.66 "**Licensed Product Patents**" means any Acceleron Patent Rights that contain claims solely directed to Licensed Compounds or Licensed Products or methods of use or manufacture thereof.

1.67 "**Licensed Product**" means any preparation in final form that contains a Licensed Compound.

1.68 "**Major Market Countries**" means the United States, the European Union, and Japan.

1.69 "**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.

1.70 "**Material Adverse Impact**" means an activity that materially adversely impacts (a) development, manufacture or commercialization (including pricing) of, with the exception of ACE-536, ActRIIB Compounds in the European Union or (b) the global pricing, regulatory, development, manufacture or commercialization strategies for, with the exception of ACE-536, ActRIIB Compounds (including product positioning) approved by the Joint Steering Committee under the Shire Agreement.

1.71 "**Net Sales**" means the aggregate gross invoice prices of all Licensed Products sold by Celgene, and its 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.

1.72 "**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.

1.73 "**Non-Developing Party**" means, with respect to any Licensed Product or Licensed Compound, the Party not conducting Development activities with respect to such Licensed Compound or Licensed Product pursuant to Section 2.1.

1.74 "**Non-Prosecuting Party**" means, with respect to a particular Patent Right, the Party which is not the Prosecuting Party.

1.75 "**North America**" means the United States, including its territories and possessions, Canada and Mexico.

1.76 "**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(d), and 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.

1.77 "**Option Compound Development Costs**" means, with respect to an Option Compound, the amount of Development Costs incurred by Acceleron in the Development of such Option Compound. For the purposes of this Section 1.77, the definition of each of "Development Costs" and "Development" shall be deemed to apply to Option Compounds *mutatis mutandis* as it applies to Licensed Compounds and Licensed Products *(i.e.,* substituting "Option Compounds" for "Licensed Compounds" or "Licensed Products").

1.78 "**Option Compounds**" means any compound (a) that is not (i) a Licensed Compound hereunder or (ii) a "Licensed Compound," "Licensed Product," or "Option Compound" under the ACE-011 Agreement, (b) that is Controlled by Acceleron, and (c) for which Acceleron has submitted an IND (which is accepted by the applicable Regulatory Authority) for Use in Anemia; provided that, notwithstanding anything to the contrary in this Agreement, Acceleron shall not be deemed to Control any additional Option Compounds following a Change of Control of Acceleron that were not Controlled by Acceleron prior to such Change of Control.

1.79 "**Option Patent Rights**" means any Patent Rights Controlled by Acceleron as of the Effective Date or during the Agreement Term, other than a Patent Right that is otherwise already an Acceleron Patent Right (including those on Schedule 1.5 as of the Effective Date), solely to the extent that such Patent Rights (a) claim the manufacture or use of in the Field, (b) claim a composition of matter of or including, or (c) are necessary or useful to Develop, Manufacture or Commercialize in the Field, in each case, (i) an Option Compound which is deemed a Licensed Compound in accordance with Article 7 or (ii) a Licensed Product containing such Licensed Compound described in clause (a)(i) of this Section 1.79. For the avoidance of doubt, any Patent Rights that claim the use of an Option Compound which is deemed a Licensed Compound in

combination with another product (including the use of such Option Compound as part of a Combination Product) shall be included within "Option Patent Rights" (if otherwise within this definition); provided that such inclusion shall not cause "Option 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 an Option Compound which is deemed a Licensed Compound.

1.80 "**Option Product**" means any preparation in final form that contains an Option Compound.

1.81 "**Option Term**" means the period of time beginning on the Effective Date and ending on the later of (a) 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 under this Agreement during the Agreement Term; (b) the date on which (i) no development or commercialization activities for any "Licensed Compound" or "Licensed Product" (each as defined in the ACE-011 Agreement) under the ACE-011 Agreement are ongoing and, according to the applicable development and commercialization committees thereunder, no additional development or commercialization activities, respectively, are expected to commence under the ACE-011 Agreement during its term and (ii) all option rights under the ACE-011 Agreement have been forfeited with respect to each "Option Compound" with respect to which Celgene has made an "Option Program Payment" to Acceleron (as each such term is defined in the ACE-011 Agreement) as of the date of the events described in clause (i); and (c) the date on which the Royalty Term for all Licensed Products under this Agreement and the "Royalty Term" (as defined in the ACE-011 Agreement) for all "Licensed Products" (as defined in the ACE-011 Agreement) has ended; provided that, if, at the time that the Option Term would otherwise end, any Option is then pending pursuant to Section 7.2 or 7.2.4, then the "Option Term" shall continue until the termination of the Option pursuant to Section 7.2.3 or 7.2.4 without Celgene having exercised the Option. For the avoidance of doubt, (x) if Celgene exercises such Option, then the conditions set forth in clause (a)(i) shall no longer be deemed to have been met at such time; and (y) if Acceleron has designated an Option Compound in accordance with Section 7.2.1 and Celgene elects not to exercise its Option at such time, the Option shall not be deemed to have terminated under Section 7.2.3 until completion of the first Clinical Trial for such Option Compound pursuant to Section 7.2.2.

1.82 "**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.

1.83 "**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.

1.84 "**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.

1.85 "**Phase 2 Clinical Trial**" means, as to a specific pharmaceutical product, a 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 2 Clinical Trials or Phase 3 Clinical Trials, as further defined in 21 C.F.R. 312.21(b) or the corresponding regulation in jurisdictions other than the United States. A Phase 2 Clinical Trial shall be deemed initiated upon the dosing of the first patient.

1.86 "**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.

1.87 "**PHS Act**" means the United States Public Health Service Act, as amended, and the rules and regulations promulgated thereunder.

1.88 "**Post-Approval Clinical Trial**" means (a) any Clinical Trial conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval and (b) 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.

1.89 "**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.

1.90 "**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.

1.91 "**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 Section 8.2 .1 (a)(i).

1.92 "**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.

1.93 "**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 EMA.

1.94 "**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.

1.95 "**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.

1.96 "**Shire**" means Shire AG, or its successor or assign under the Shire Agreement.

1.97 "**Shire Agreement**" means the License and Collaboration Agreement by and between Acceleron Pharma, Inc. and Shire AG dated as of September 8, 2010, as such agreement may be amended from time to time in accordance with Section 4.5.4.

1.98 "**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.

1.99 "**Territory**" means all the countries of the world.

1.100 "**TGFB Compound**" means any molecule or molecules, other than ActRIIB Compounds, which work directly on: (a) a ligand; (b) a binding partner of a ligand; and/or (c) a receptor, in each case, of the TGF Beta superfamily pathway members. For the avoidance of doubt, "TGFB Compound" shall not include (i) ACE-536 or (ii) a "Licensed Compound," "Licensed Product," or "Option Compound" under the ACE-011 Agreement.

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 any 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 "**Third Party Licenses**" means the license agreements, entered into by Acceleron prior to the Effective Date, including any amendments thereto as of the Effective Date, pursuant to which Acceleron Controls Acceleron Technology, as specified on Schedule 1.104.

1.105 "**Third Party Licensor**" means the Third Party licensor(s) of Third Party Intellectual Property from whom Acceleron has licensed intellectual property rights pursuant to a Third Party License.

1.106 "**Triggering Event**" means any of the following events: (a) the filing or institution of a voluntary or involuntary bankruptcy, reorganization, liquidation or receivership proceedings, or an assignment of a substantial portion of the assets for the benefit of creditors by or against Acceleron; (b) Acceleron's reasonable belief that any event detailed in Section 1.106(a) may occur within the next [* * *]; (c) there is an occurrence and continuance (for a period in excess of any applicable cure period following notice thereof) of a default by Acceleron with respect to any of its debt or payment obligations in excess of $[* * *] or any agreement having a material adverse effect on Acceleron's business or Acceleron's ability to perform under this Agreement; (d) for [* * *], Acceleron fails to have sufficient available cash to fund the next [* * *] of its budgeted operating expenses, based on the budget approved by Acceleron pursuant to Section 2.3 of the Amended and Restated Investor Rights Agreement among Acceleron and certain stockholders, dated as of March 24, 2008 and as amended ("**IRA**"); (e) Acceleron plans to take any action that would give Celgene a termination right under Section 10.2.1(b); or (f) one or more creditors of Acceleron notify Acceleron in writing that such creditors have organized for the purpose of commencing negotiations with regard to a possible bankruptcy filing of Acceleron, or Acceleron has commenced negotiations with one or more creditors with regard to a possible bankruptcy filing of Acceleron. Celgene shall have the right to use the information contained within the financial reports delivered in accordance with the IRA in determining whether or not a Triggering Event has or has not occurred.

1.107 "**U.S. GAAP**" means generally accepted accounting principles in the United States.

1.108 "**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.

1.109 "**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.

1.110 **Additional Definitions.** The following terms have the meanings set forth in the corresponding Sections of this Agreement:

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Term	Section
"**Acceleron Indemnitees**"	11.7.1
"**Acceleron NA Operating Costs**"	5.5.3(b)
"**Agreement**"	Introduction
"**Acquired Party Activity**"	6.3
"**Audited Party**"	5.7.4(b)
"**Auditing Party**"	5.7.4(b)
"**Breaching Party**"	10.2.1(a)
"**Celgene Indemnitees**"	11.7.2
"**Commercialization Plan/Budget**"	2.5
"**Defending Party**"	8.4.3
"**Extensions**"	8.9
"**Indemnitee**"	11.7.3
"**Infringement Claim**"	8.4.1
"**IP**"	10.8
"**JCC Chairperson"**	3.2.3
"**JDC Chairperson**"	3.1.3
"**Joint Development Committee**"	3.1.1
"**Joint Commercialization Committee**"	3.2.1
"**Losses**"	11.7.1
"**Option**"	7.2.1
"**Original Agreement"**	Recitals
"**Pre-IND Anemia Compounds**"	7.2.4(a)(ii)
"**Prosecuting**" or "**Prosecution**"	8.2.1(a)(i)
"**Publishing Party**"	9.2
"**Reconciliation Statement**"	5.5.5
"**Royalty Report**"	5.6.4
"**Third Party Intellectual Property Notice**"	5.6.3(d)
"**Third Party Patent Rights**"	8.1.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Article 2
COLLABORATION

2.1 **Development.**

2.1.1. Acceleron Responsibilities. Subject to the oversight of the Joint Development Committee and Section 2.1.3, Acceleron shall be solely responsible for managing all Acceleron Development Activities relating to Licensed Compounds or Licensed Products for the treatment of Initial Development Diseases and any Additional Development Diseases approved by the Joint Development Committee pursuant to Section 2.1.3, each in the Territory. Any Acceleron Phase 2 Clinical Trial not initiated *(i.e.,* dosing of first patient) by the third anniversary of the Effective Date shall not be included within the definition of Acceleron Phase 2 Clinical Trials. 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 for the treatment of Initial Development Diseases and any Additional Development Diseases approved by the Joint Development Committee for Development pursuant to Section 2.1.3. Except to the extent Celgene has assumed Development responsibilities pursuant to Section 2.1.2, Acceleron shall use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for Licensed Products for the Initial Development Diseases and any Additional Development Diseases approved by the Joint Development Committee for Development pursuant to Section 2.1.3 in the Major Market Countries.

2.1.2. Celgene Responsibilities.

(a) Election. Celgene may, by providing written notice to the Joint Development Committee, elect to be solely responsible for conducting, subject to Section 2.1.2(d), all Development activities of a Licensed Compound or related Licensed Product in the Field upon the earliest to occur of the following:

(i) [* * *];

(ii) following the Joint Development Committee's decision to go forward with a Phase 3 Clinical Trial of such Licensed Compound or Licensed Product;

(iii) within [* * *] of (x) a consummated Change of Control of Acceleron or (y) the occurrence of any Triggering Event; provided that, if Acceleron fails to provide Celgene with written notice of such Change of Control or Triggering Event, such [* * *] period shall not commence until Acceleron provides such notice; or

(iv) with respect to any Option Compound deemed a Licensed Compound in accordance with Article 7 (or any Licensed Product that contains such Licensed Compound), at any time following Celgene's exercise of its Option;

provided that, except upon the occurrence of the event described in clause (iii) above, notwithstanding Celgene's election to assume responsibility in connection with the occurrence of the event described in clause (i) or (ii) above, Acceleron shall retain responsibility for conducting all Development activities relating to the conduct of the Acceleron Phase 2 Clinical Trials through Completion thereof. For the avoidance of doubt, (1) Acceleron shall conduct all Development activities with respect to a Licensed Compound and related Licensed Product, and shall be the Developing Party for such Licensed Compound, prior to an election by Celgene pursuant to this Section 2.1.2(a) with respect to such Licensed Compound; and (2) Celgene shall, subject to Section 2.4, conduct all Development activities with respect to a Licensed Compound and related Licensed Product (subject to the immediately prior sentence), and shall be a Developing Party for such Licensed Compound, following an election by Celgene pursuant to this Section 2.1.2(a) with respect to such Licensed Compound.

(b) After Regulatory Approval. Celgene shall be solely responsible for conducting all Development activities of a Licensed Product in the Field following such Licensed Product's receipt of Regulatory Approval in any country in the Territory.

(c) Obligations. 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. 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. With respect to those Licensed Products for which Celgene has assumed Development pursuant to Section 2.1.2(a), 2.1.2(b) or 2.1.2(e), Celgene shall use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for such Licensed Products in the Major Market Countries.

(d) Scope of Development Activities Transferred. Notwithstanding anything to the contrary in this Agreement, Celgene's assumption of Development activities pursuant to this Section 2.1.2 shall not include any transfer of Manufacturing responsibilities, such transfer to be governed by Section 2.4.

(e) Upon Acquisition of Acceleron by Certain Third Parties. Subsequent to an acquisition of Acceleron by a designated Third Party set forth in Schedule 3.7, Celgene shall be solely responsible for conducting all Development activities of each Licensed Compound or related Licensed Product in the Field.

2.1.3. Restrictions on Development; Additional Development Diseases. Either Party may submit a request in writing to the Joint Development Committee that the Developing Party conduct Development of a Licensed Compound or any Licensed Product containing such Licensed Compound for Additional Development Disease. Upon such request, the Joint Development Committee shall decide within sixty (60) days as to whether the Developing Party shall conduct such Development, and, if such Development is

approved, the Joint Development Committee shall amend the Development Plan/Budget as necessary to reflect such additional Development. Except as approved by the Joint Development Committee or otherwise agreed to by the Parties, Acceleron and its Affiliates shall not, directly or indirectly with a Third Party, Develop any Licensed Compound or Licensed Product for Additional Development Diseases during the Agreement Term.

2.1.4. Development Plan/Budget.

(a) Generally. 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.

(b) Acceleron Phase 2 Clinical Trials. With respect to an Acceleron Phase 2 Clinical Trial, independent of the rest of the Development Plan/Budget, Acceleron shall prepare a proposal for a budget to apply to each such Clinical Trial and present it to the Joint Development Committee. For an Acceleron Phase 2 Clinical Trial, Acceleron will prepare a protocol for such Clinical Trial which is consistent with industry standards for a similarly-situated product, including with respect to scope, cost, duration of treatment and size of subject population. The Joint Development Committee shall then review Acceleron's proposal and approve a reasonable budget for such Acceleron Phase 2 Clinical Trial. If an Acceleron Phase 2 Clinical Trial is put on Clinical Hold, the Joint Development Committee shall modify the budget to appropriately reflect the costs associated with the wind-down of activities associated with the applicable Acceleron Phase 2 Clinical Trial.

2.1.5. Payment of Development Costs. The Parties shall share Development Costs and other costs associated with Development in accordance with Section 5.5.

2.1.6. Consultation. If and for so long as Celgene Development Activities are ongoing under this Agreement, Celgene agrees to consult with Acceleron with respect to the Development of Licensed Products and Licensed Compounds in accordance with the provisions of Section 2.9.4.

2.2 **Records.**

2.2.1. Generally. 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; provided 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 Article 9.

2.2.2. Security. 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.

2.2.3. Electronic Records. Each Party will maintain records related to the collaboration in electronic form. Notwithstanding the foregoing, Acceleron laboratory notebooks are kept in paper form and shall be regularly converted to electronic form.

2.3 **Regulatory Matters.**

2.3.1. General. With respect to any Licensed Compound or Licensed Product, the Developing Party shall develop a regulatory strategy and prepare all submissions, documents or other correspondence to be submitted to the applicable Regulatory Authorities for such Licensed Compound or Licensed Product in the Territory; provided that such regulatory strategy shall be performed by the Developing Party in consultation with the Joint Development Committee. The Parties acknowledge that, if there is more than one Developing Party for the same Licensed Compound or Licensed Product, each Developing Party's rights and responsibilities under this Section 2.3 shall apply to such Developing Party's Development activities.

2.3.2. Responsibility. A Developing Party (with respect to the Clinical Trials for which it is responsible hereunder) shall have primary responsibility to oversee, monitor, coordinate, file, and hold in its name all INDs, all communications with and submissions to Regulatory Authorities in the Territory with respect to a Licensed Compound or Licensed Product and all Regulatory Approvals of a Licensed Product and Licensed Compound in the Territory; provided that, if Acceleron is the Developing Party, all such

oversight, monitoring, coordination, and filing shall be done with the review of Celgene and giving good faith consideration to Celgene's comments. All costs associated with such activities will be shared by the Parties in accordance with Article 5, including Section 5.5. To the extent Celgene initiates a Clinical Trial under an IND held by Acceleron, Acceleron shall maintain its responsibilities set forth in this Section 2.3.2 and continue to hold such IND, subject to Section 2.3.5.

2.3.3. Regulatory Meetings and Correspondence. A Developing Party (with respect to the Clinical Trials for which it is responsible hereunder) shall have primary responsibility for interfacing, corresponding and meeting with the applicable Regulatory Authorities with respect to a Licensed Compound or Licensed Product in the Territory. The Non-Developing Party shall be entitled to participate in all material or planned meetings and telephonic discussions between representatives of the Developing Party and the applicable Regulatory Authorities with respect to Licensed Compounds or Licensed Products in the Territory and, to the extent practicable, all other such meetings and discussions. For purposes of clarification, the Developing Party agrees to use Commercially Reasonable Efforts to notify the Non-Developing Party of planned meetings and telephonic discussions with such Regulatory Authorities and to use Commercially Reasonable Efforts to accommodate the schedule of the Non-Developing Party's attendees at such meetings or discussions. The Developing Party shall be entitled to limit, but not entirely exclude, the number of representatives of the Non-Developing Party that attend meetings and telephonic discussions with applicable Regulatory Authorities in the Territory.

2.3.4. Review of Correspondence. To the extent practicable, the Developing Party shall provide the Non-Developing Party with drafts of any documents or other correspondence to be submitted to the applicable Regulatory Authorities with respect to a Licensed Compound or Licensed Product or in connection with any Development activity of the Non-Developing Party, sufficiently in advance of submission for the Non-Developing Party to review any such submission, and the Non-Developing Party may comment on such documents, in which case the Developing Party shall consider in good faith all such comments. The Developing Party shall provide to the Non-Developing Party as soon as reasonably practicable, copies of any documents or other correspondence received from Regulatory Authorities with respect to a Licensed Compound or Licensed Product or in connection with any Development activity of the Non-Developing Party (including any meeting minutes).

2.3.5. Transfer. Upon Celgene's designation as the Developing Party as to a Licensed Compound or Licensed Product pursuant to Section 2.1, Acceleron shall promptly take the actions reasonably necessary to transfer ownership and, as applicable, physical possession of all material regulatory filings, correspondence and related information (including any INDs, NDAs, and other Regulatory Approvals) for such Licensed Compound or Licensed Product in the Territory and shall notify the appropriate Regulatory Authorities of such transfer of ownership. All costs associated with such actions of Acceleron will be shared by the Parties in accordance with Article 5, including Section 5.5; provided, however, if Celgene initiates a Clinical Trial under an IND held by

Acceleron which is in the same disease as the Initial Development Disease and for which Acceleron has not completed such Clinical Trial, Acceleron shall transfer such IND promptly after the completion *(i.e.,* the last patient has completed the last dosing) of such Clinical Trial in accordance with this Section 2.3.5.

2.4 **Manufacture and Supply.**

2.4.1. Phase 1 and 2 Clinical Supply. Subject to Section 2.4.2, Acceleron shall Manufacture all Clinical Supplies for Phase 1 Clinical Trials and Phase 2 Clinical Trials. If Celgene is a Developing Party, the terms of supply of Clinical Supplies to Celgene pursuant to this Section are set forth in Exhibit A, 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 or Phase 2 Clinical Trials. At any time upon Celgene's request, Acceleron shall assist Celgene in obtaining a second source for supply of Clinical Supplies, which second source will be available to supply the Parties with Clinical Supplies if Acceleron fails to so supply Celgene in accordance with the provisions of Exhibit A or fails to so supply Acceleron itself, or as otherwise agreed to by the Parties, with the costs of such second source shared in accordance with Section 5.5.1. Notwithstanding the foregoing, subsequent to an acquisition of Acceleron by a designated Third Party set forth in Schedule 3.7, Celgene may, within [* * *], provide Acceleron with written notice, at Celgene's sole discretion, instructing Acceleron to cease all Manufacturing activities hereunder.

2.4.2. Phase 3 Clinical Supply. Celgene shall Manufacture and supply all Clinical Supplies for Phase 3 Clinical Trials and Post-Approval Clinical Trials; provided that

(a) Celgene may request of Acceleron (or Acceleron may request of Celgene), at least one (1) year prior to the anticipated initiation of the first Phase 3 Clinical Trial for a Licensed Compound or Licensed Product, that Acceleron Manufacture and supply Clinical Supplies of such Licensed Compound or Licensed Product on terms to be agreed, which may include provisions related to the use of such material for launch and a portion of Commercial Supplies for a period thereafter on financial terms to be mutually agreed upon by the Parties. 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, and otherwise the Costs of Clinical Supplies shall be allocated in accordance with Article 5, including Section 5.5.

(b) Within [* * *] of (i) a consummated Change of Control of Acceleron or (ii) the occurrence of any Triggering Event, Celgene, may, by written notice to Acceleron, assume responsibility for Manufacture and supply of all Clinical Supplies for all Clinical Trials (including all Phase 1 Clinical Trials and Phase 2 Clinical Trials) and upon such request, Celgene shall be responsible for the

Manufacture and supply of such Clinical Supplies; provided that, if Acceleron fails to provide Celgene with written notice of such Change of Control or Triggering Event, such [* * *] period shall not commence until Acceleron provides such notice.

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 or Phase 2 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. Commercial Supply. Celgene shall Manufacture and supply all Commercial Supplies.

2.4.4. Manufacturing Generally. 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.

2.4.5. Process Development. The Development Plan/Budget for the first two (2) Contract Years shall include activities to optimize the current Manufacturing process and undertake analytical method development activities for ACE-536. Such optimization shall include scaling up the titer (which currently is at [* * *]) to a target of [* * *]. At Acceleron's election, Acceleron may utilize the services of a Third Party, reasonably acceptable to Celgene, to conduct such optimization and analytical method development activities, and the costs of such Third Party, as approved as part of the Development Plan/Budget, shall be shared in accordance with Section 5.5.1. During this process, Acceleron shall share with Celgene information regarding the optimization and analytical methods development and consult with Celgene in connection therewith.

2.4.6. Information Sharing. From time to time as the Parties deem reasonable to ensure timely and proper completion of Development activities, the CMC groups of each Party may meet to share information and work collaboratively to develop the Manufacturing process.

2.4.7. Tech Transfer. Celgene may request, in the form of written notice to Acceleron, a transfer of relevant Acceleron Technology (a) with respect to all Clinical Supplies upon Celgene's election pursuant to Section 2.4.2(b) to assume Manufacturing responsibilities for all Clinical Supplies, (b) with respect to Clinical Supplies of a Licensed Compound or Licensed Product prior to or following the initiation of a Phase 2 Clinical Trial of such Licensed Compound or Licensed Product, with the costs of such other transfer shared in accordance with Section 5.5.1, (c) to the second source identified pursuant to Section

2.4.1, or (d) at such other time as is requested by Celgene, with the costs of such other transfer shared in accordance with Section 5.5.1. Within thirty (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 the applicable 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.

2.5 **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. On a Licensed Product-by-Licensed Product basis, Celgene shall use Commercially Reasonable Efforts to Commercialize all Licensed Products in each country in the Territory outside North America in which Regulatory Approval for such 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. Commercialization Activities. Within North America, the Parties will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field. In addition, within North America and subject to Section 2.7.6, 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. 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. Sales Representatives. 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; provided 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 [* * *] (which sales representatives, to the extent practicable, will be the sales representatives used by Acceleron under the ACE-011 Agreement) 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 [* * *] (which detailing efforts, to the extent practicable, will be to the same prescribing physicians as allocated to Acceleron under the ACE-011 Agreement). The Joint Commercialization Committee will attempt to provide that each Party'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; provided further that such detailing efforts, to the extent practicable, will be distributed in the same manner as the ACE-011 Agreement. The Sales Force Costs of Acceleron will be reimbursed pursuant to a rate set forth in the Commercialization Plan/Budget.

2.7.3. Sales Force. 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; provided 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. Training Materials and Sessions. 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, which meetings shall be held simultaneously with field management meetings under the ACE-011 Agreement to the extent practicable. 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, which meetings and training events will be held in conjunction with Acceleron's similar meetings under the ACE-011 Agreement to the extent practicable.

2.7.5. Promotional Materials. 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. Termination of Acceleron Sales Force Cost Reimbursement. 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 Section 5.5.1(b) (or Section 2.7.2) 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. Utilization of Third Parties. 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 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. Requirements of Third Parties. 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. Tech Transfer. In addition to the provisions of Section 2.4.7, 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. Reports By Celgene. Celgene shall keep Acceleron reasonably informed about the status of the activities performed with respect to Regulatory Approvals of Licensed Products in the Territory, and the status of Celgene's Commercialization activities outside of North America.

2.9.4. Meetings. [* * *], 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.

2.9.5. Cessation of Reporting. Subsequent to an acquisition of Acceleron by a designated Third Party set forth in Schedule 3.7, Celgene's obligation to provide reports under Article 2 and Article 3 shall cease; provided, however, that Celgene shall continue

to provide reports under Section 2.9.3 and semiannual reports regarding Development of Licensed Products.

2.10 **ACE-011 Agreement.** Following the Completion of the Acceleron Phase 2 Clinical Trials and 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-011 Agreement instead of Developing and Commercializing a Licensed Compound or Licensed Product under this Agreement or (b) to Develop a Licensed Compound or Licensed Product hereunder instead of a "Licensed Compound" or "Licensed Product" under the ACE-011 Agreement, and, thereafter, if Celgene is undertaking "Development" or "Commercialization" (each as defined in the ACE-011 Agreement) activities in accordance with the ACE-011 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-011 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. Establishment. 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 Membership. 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 Section 3.1.5 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; 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 Development 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.

3.1.3. Chairperson. The Chairperson of the Joint Development Committee (the "**JDC Chairperson**") shall be Acceleron's representative until Celgene is the Developing Party of a Licensed Product pursuant to this Agreement, at which time Celgene's representative shall become the JDC Chairperson. The JDC Chairperson's responsibilities shall include (a) scheduling meetings; (b) setting agendas for meetings with solicited input from the other Party'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. Meetings. 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. Responsibilities. 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 2.1.4;

(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(d);

(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. Establishment. 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 of Licensed Products and comply with the instructions of Celgene on behalf of the Joint Commercialization Committee, as provided herein.

3.2.3. Chairperson. 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. Meetings. 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); provided 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 Section 2.5. 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 Section 2.5, 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 Section 5.6.3(d);

(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.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

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 as follows:

(a) if such issue properly originated at the Joint Development Committee, determined by the Developing Party of the relevant Licensed Compound or Licensed Product at issue; provided that, notwithstanding the foregoing:

(i) if Acceleron is the Developing Party and such issue relates to (x) the approval of an Additional Development Disease, or (y) matters under Section 5.6.3(d), then such issue shall be determined by [* * *];

(ii) regardless of which Party is the Developing Party, such issue shall be determined by [* * *] following the earliest of: (x) [* * *], and (y) the

Joint Development Committee's decision to go forward with a Phase 3 Clinical Trial of the relevant Licensed Compound or Licensed Product; provided that [* * *] shall continue to determine any issues that relate to the budget for and the conduct of the [* * *]; and

(iii) regardless of which Party is the Developing Party, such issue shall be determined by [* * *] following the earliest of: (x) [* * *], and (y) the occurrence of any [* * *]; and

(b) if such issue properly originated at the Joint Commercialization Committee, determined by Celgene.

Notwithstanding the foregoing, none of Acceleron, Celgene, the Joint Development Committee or 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 [* * *], then such matter shall be resolved in accordance with Section 12.1 hereof.

3.7 **Dissolution.** The Joint Development Committee and Joint Commercialization Committee shall each be dissolved upon (a) expiration of the Agreement Term, (b) or at any earlier time upon mutual written agreement of the Parties, or (c) subsequent to an acquisition of Acceleron by a designated Third Party set forth in Schedule 3.7. In the event of such dissolution in accordance with Section 3.7(b) or 3.7(c), 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 Celgene's obligations under Article 2 and Article 3 (i) to report or share with Acceleron the Development Plan/Budget and Commercialization Plan/Budget, and (ii) 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.

3.8 **Appointment of Joint Development Committee and Joint Commercialization Committee Members.** Notwithstanding the above, at all times after [* * *] 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 [* * *] 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. Celgene's Right to Sublicense. Celgene may sublicense the rights granted to it under Section 4.1, in whole or in part, through one or more tiers to one or more of its Affiliates or Third Parties at any time. In the event that Celgene enters into any sublicense (other than a sublicense to an Affiliate) in whole or in part, then, such sublicense shall not modify Acceleron's rights under this Agreement with respect to participating in collaboration matters as provided in Article 2 (Collaboration) and Article 3 (Collaboration Management) or under the cost sharing provisions of Section 5.5. 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 [* * *] after such agreement has been fully executed) after execution of such sublicense, 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. All such notices and copies of sublicenses provided by Celgene under this Section 4.3.1 shall be deemed to be Confidential Information of Celgene subject to the provisions of Article 9 hereof whether or not so marked.

4.3.2. Terms. Each sublicense granted by Celgene pursuant to Section 4.3.1 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 Section 5.7.4; and (c) a requirement that such Sublicensee comply with the confidentiality and non-use provisions of Article 9 with respect to Acceleron's Confidential Information.

4.3.3. Effect of Termination. 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; provided, however, that such Sublicensee is not in breach of its sublicense 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. Joint Improvements/Collaboration IP. 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. Data. All data generated in the course of Clinical Trials hereunder shall be owned by Celgene and deemed "Celgene Know-How"; provided that the foregoing shall not apply to Clinical Trials conducted with respect to any Option Compound prior to Celgene's exercise of its Option to such Option Compound. 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. Celgene IP. Celgene is and shall remain the sole owner of the Celgene Technology.

4.4.5. Acceleron IP. Acceleron is and shall remain the sole owner of the Acceleron Technology.

4.4.6. Disputes as to Inventorship and Ownership of Improvements and Collaboration IP. 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 Schedule 4.4.6 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 **Third Party License(s); Shire Agreement.**

4.5.1. Acknowledgement. Acceleron acknowledges that it is responsible for the fulfillment of its obligations under the Third Party License(s) and agrees to fulfill 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 Third Party License(s), the Parties will discuss in good faith how to address the conflict; provided that, if the Parties are unable to agree on how to address the conflict, the terms of this Agreement shall govern. The Parties acknowledge that the Third Party License set forth on Schedule 1.104 as of the Effective Date does not permit a sublicensee to grant further sublicenses. Upon Celgene's request, Acceleron will use reasonable efforts to obtain the Third Party Licensor's consent to any further sublicense by Celgene; and, if Acceleron is not able to obtain such consent, Acceleron will grant a direct sublicense to the Person designated by, and under the terms specified by, Celgene, which shall not be inconsistent with the Third Party License or this Agreement; provided that Acceleron shall not be subject to any obligations to such Person (other than the grant of a license), and Celgene will be responsible for any license fee owed to such Third Party Licensor pursuant to Section 2 of such Third Party License as a result of such sublicense.

4.5.2. Covenants Regarding Third Party License(s). Acceleron agrees that during the Agreement Term:

(a) Acceleron shall not modify or amend any of the Third Party License(s) in any way that would adversely affect Celgene's obligations, rights or economic interest under this Agreement without Celgene's prior written consent;

(b) Acceleron shall not terminate any of the Third Party License(s) in whole or in part, without Celgene's prior written consent, if such termination would adversely affect Celgene's license granted hereunder;

(c) As between Celgene and Acceleron, Acceleron shall be solely responsible for, and shall make, all payments owed to the Third Party Licensor(s) pursuant to the Third Party License(s);

(d) Acceleron shall not, solely to the extent such action or failure to act would adversely affect Celgene's obligations, rights or economic interest under this Agreement, exercise or fail to exercise or perform any of Acceleron's rights or obligations under any of the Third Party License(s) that relate to the Licensed Compounds, Licensed Products, or Celgene's rights or obligations hereunder (including the right to negotiate with any Third Party Licensor with respect to any inventions), 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 or perform such obligations and make such requests as are permitted under each of the Third Party License(s);

(e) Acceleron shall promptly furnish Celgene with copies of all reports and other communications that Acceleron furnishes to the Third Party Licensors 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 any Third Party Licensor 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 Third Party Licenses within [* * *] after Acceleron's receipt thereof; in addition, if Acceleron should at any time breach the Third Party Licenses or become unable to timely perform its obligations thereunder, Acceleron shall immediately notify Celgene; provided that, in either case, such notice shall only be required if such breach, default, or inability to perform in any way could adversely affect Celgene's obligations, rights or economic interest under this Agreement;

(h) If Acceleron cannot or chooses not to cure or otherwise resolve any alleged breach or default under the Third Party Licenses and such breach or default in any way could adversely affect Celgene's obligations, rights or economic interest under this Agreement, Acceleron shall so notify Celgene within [* * *] of such decision, which shall not be less than [* * *] prior to the expiration of the cure period under any such Third Party License; provided that Acceleron shall use Commercially Reasonable Efforts to cure any such breach or default; and

(i) Celgene, in its sole discretion, shall be permitted to [* * *] under the Third Party Licenses in accordance with the terms and conditions of the Third Party

Licenses, or otherwise resolve such breach directly with the Third Party Licensor, if such breach or default in any way could adversely affect Celgene's obligations, rights or economic interest under this Agreement; and, if [* * *].

4.5.3. Survival of Celgene's Rights. As provided in the Third Party Licenses, in the event of termination of any Third Party License, Celgene's rights hereunder will survive in accordance with the terms of such agreement. The Parties agree that [termination of the Third Party License], without Celgene's prior written consent, shall be deemed a material breach of this Agreement by Acceleron; provided that (a) if Celgene's breach of this Agreement results in a breach of such Third Party License, Celgene agrees to use Commercially Reasonable Efforts to assist Acceleron in curing such breach, and (b) if Celgene's breach of this Agreement results in a termination of such Third Party License, such termination shall not be deemed a material breach by Acceleron of this Agreement.

4.5.4. Shire Agreement. Acceleron agrees that during the Agreement Term, without Celgene's prior written consent, Acceleron shall not modify or amend, or fail to perform under, the Shire Agreement in any way that would adversely affect Celgene's obligations, rights or economic interest under this Agreement. Acceleron shall keep Celgene reasonably informed of any notices or events under the Shire Agreement that would adversely affect Celgene's obligations, rights or economic interest under 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.** Within ten (10) days of the Effective Date, Celgene shall pay Acceleron Twenty-Five Million U.S. Dollars ($25,000,000) as an upfront, non-creditable, non-refundable fee, relating to the license grants set forth in Article 4.

5.2 **ACE-536 Development Milestones.** For any Licensed Compound or Licensed Product containing ACE-536, Celgene shall pay to Acceleron the amounts set forth below no later than [* * *] after the earliest date on which the corresponding milestone event has first been achieved with respect to such a Licensed Compound or Licensed Product containing ACE-536 described below:

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Milestone Event	*Payment*
Dosing the first subject in the first multiple dose Clinical Trial	$7,500,000
Dosing the first patient in the first Phase 2 Clinical Trial	$10,000,000
Dosing the first patient in the first Phase 3 Clinical Trial	$15,000,000
Acceptance of the first NDA by the FDA or EMA for use of a Licensed Product	$25,000,000
Approval of the first NDA by the FDA for use of a Licensed Product	$35,000,000
Approval of the first NDA by the EMA for use of a Licensed Product	$25,000,000
Approval of the first NDA by a Regulatory Authority in Asia for use of a Licensed Product	$20,000,000

For clarity, the milestone payments set forth in this Section 5.2 shall be paid only once regardless of how many Licensed Product containing ACE-536 achieve the milestone or how many times that a Licensed Compound or Licensed Product containing ACE-536 may achieve the milestone event, and regardless of whether such a Licensed Compound or Licensed Product achieves the milestone event more than once for the same or different indication. Furthermore, to the extent a Licensed Compound or Licensed Product containing ACE-536 fails and a replacement Licensed Compound or Licensed Product containing ACE-536 is selected, any milestones previously paid for such failed Licensed Compound or Licensed Product shall not be paid again 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 [* * *] shall not be deemed to trigger any milestone payment for [* * *].

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

5.3 **Option Compound Development Milestones.** For any Licensed Compound or Licensed Product containing an Option Compound which is deemed a Licensed Compound in accordance with Article 7 or a Licensed Product containing such Licensed Compound, Celgene shall pay to Acceleron the amounts set forth below no later than [* * *] after the earliest date on which the corresponding milestone event has first been achieved with respect to any such Licensed Compound or Licensed Product containing an Option Compound (for the avoidance of doubt, the milestones set forth below shall be payable separately with respect to each Option Compound (but not separately for an Option Compound and Licensed Product that contains such Option Compound)):

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Milestone Event	*Payment for first Option Compound licensed to Celgene*	*Payment for second Option Compound licensed to Celgene*	*Payment for third and succeeding Option Compounds licensed to Celgene*
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]
[* * *]	$[* * *]	$[* * *]	$[* * *]

For clarity, the milestone payments set forth in this Section 5.3 shall be paid only once for each Licensed Compound or Licensed Product the underlying Licensed Compound of which is the same Option Compound, regardless of how many Licensed Compounds and Licensed Products with the same Option Compound may achieve the milestone event and regardless of whether the same Licensed Compound or Licensed Product achieves the milestone event more than once for the same or different indication. By way of a nonlimiting example, if a Licensed Compound and a Licensed Product containing the same Option Compound achieve the same milestone event, only one payment is due. Furthermore, to the extent a Licensed Compound or Licensed Product fails or is discontinued and the Parties agree upon a replacement Licensed Compound or Licensed Product containing the same Option Compound or a back up thereof to be substituted for the original Option Compound, 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 by a Licensed Compound or Licensed Product, then upon the achievement of such subsequent milestone by such Licensed Compound or Licensed Product all preceding unpaid milestone payments for such Licensed Compound or Licensed Product shall be made in addition to the payment corresponding to the milestone that has been achieved; provided that [* * *] shall not be deemed to trigger any milestone payment for [* * *].

For the avoidance of doubt, payments under this Section 5.3 for the achievement of milestone events shall only be due for milestone events achieved following the exercise by Celgene of the relevant Option for each Option Compound which is deemed a Licensed Compound in accordance with Article 7 or a Licensed Product containing such Licensed Compound. For the avoidance of doubt, the determination of which is the first, second, third, and succeeding Option Compounds shall be based on the date that each Option Compound is deemed a Licensed Compound in accordance with Article 7.

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

Milestone Event	*Payment*
[* * *]	$[* * *]
[* * *]	$[* * *]

Once Celgene has made any particular milestone payment under this Section 5.4, Celgene shall not be obligated to make any payment under this Section 5.4 with respect to the reoccurrence 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 Section 5.4, Net Sales shall be derived from audited financial statements of Celgene (or the applicable Affiliate or Sublicensee); provided, however, 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 Sections 5.5.1(b)(ii) through (iv), for all 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 Development Costs.

(b) Celgene shall be responsible for paying one hundred percent (100%) of (i) all Development Costs incurred on or after January 1, 2013, (ii) all Development Costs associated with obtaining a second source of supply of Clinical Supplies pursuant to Section 2.4.1, (iii) [* * *] Development Costs associated with completing a transfer of relevant Acceleron Technology pursuant to Section 2.4.7(b) or 2.4.7(d), (iv) all Development Costs associated with using a Third Party to complete optimization and analytical method development pursuant to Section 2.4.5 to the extent such Development Costs exceed $[* * *], and (v) [* * *]; provided that the Parties acknowledge and agree that Acceleron will not be incurring any such costs described in clause (v) (other than [* * *] or other [* * *] that are specifically set forth in the [* * *].

(c) Patent Procurement Costs shall be shared in accordance with the provisions of Section 8.2.4.

(d) Except for approved costs incurred by Acceleron pursuant to Section 2.4.2, 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. Sharing Mechanics. 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 Article 5 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. Cost Reporting.

(a) Development Costs. No later than [* * *] Business Days after the end of each Contract Quarter, each Party shall report to the other Party an estimate of its 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 Section 8.2.4). 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 Development Costs and Patent Procurement Costs (for which reimbursement is required pursuant to Section 8.2.4). Notwithstanding the

foregoing, Celgene shall have no obligation to report to Acceleron Celgene's estimated or actual Development Costs incurred on or after January 1, 2013, though Celgene will continue to report any Patent Procurement Costs as described in this Section 5.5.3(a).

(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 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 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 therefor, 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 Section 5.5.4 shall not apply to Development Costs incurred by Celgene on or after January 1, 2013.

5.5.5. Reconciliation Statements. In addition to providing its report of 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 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 Development Costs incurred 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. Royalty Percentages. Subject to this Section 5.6, for sales of Licensed Products in the Territory, Celgene shall retain all amounts received for such sales; provided 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 [* * *];

provided further 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. Cumulative Royalties. 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) Buy-Down. Immediately upon payment by Celgene of the "Buy-Down Payment" (as defined in the ACE-011 Agreement) pursuant to the ACE-011 Agreement, the royalty payments to be paid by Celgene to Acceleron under Section 5.6.1 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(a) shall be subject to reduction pursuant to Section 5.6.3(b) through Section 5.6.3(d).]

(b) Know-How Only or Generic Competition. 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 not 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 Section 5.6.1 (or, as applicable, Section 5.6.3(a)) for such Licensed Product in such country shall be reduced by [* * *] percent [* * *] for the remainder of the Royalty Term. For the avoidance of doubt, the Parties acknowledge and agree that Celgene shall have no obligation hereunder to pay royalties on Net Sales if (x) the offering for sale, selling, making, having made, using or importing of a Licensed Product is not covered by a Valid Claim of an Acceleron Patent Right in such country and (y) such Manufacture, use or sale of a Licensed Product is not covered by Acceleron Know-How.

(c) Celgene Third Party Licenses. 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 [* * *] percent [* * *] 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 Section 5.6.3(d)) with respect to a particular Licensed Product against amounts Celgene is obligated to pay Acceleron under Section 5.4 or Section 5.6.1 (or, as applicable, Section 5.6.3(a)) for such Licensed Product; provided that in no such event shall any such offset reduce by more than [* * *] percent [* * *] the payments otherwise due to

Acceleron in particular Contract Years; provided further 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(c) 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.

(d) 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 Third Party Intellectual Property in the same way as the Third Party Licenses (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, (y) 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(c). 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.

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 Quarter.

(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 Section 5.7.3, 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.

(b) 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 occur not more than [* * *] 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. Payments Between the Parties. 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. 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 [* * *] 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 [* * *].

6.1.2. In any Third Party license, development, research, collaboration, commercialization or similar agreement with respect to any product, Acceleron 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 Acceleron 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.

6.1.3. Notwithstanding the foregoing, the provisions of Section 6.1.1 and 6.1.2 shall not apply to Acceleron or its Affiliates to the extent of (a) conducting the activities required to fulfill Acceleron's obligations hereunder or under the ACE-011 Agreement or (b) developing Option Compounds pursuant to Section 7.2.1 or 7.2.2.

6.1.4. Notwithstanding the foregoing, the provisions of Section 6.1.1 or 6.1.2 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 [* * *], Inc., 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 Sections 6.1.1 and 6.1.2; (b) if Acceleron agrees to collaborate with [* * *] on the identification, research and development of any product or compound (other than the [* * *] (as each term is defined in the [* * *] Agreement as of the date hereof)) shall be subject to the provisions of Section 6.1.1 and 6.1.2. Acceleron represents and warrants to Celgene that neither the [* * *] nor [* * *] is a [* * *] (as defined in the Alkermes Agreement as of the date hereof).

6.2 **Third Party Acquisitions.** The provisions of this Article 6 do not apply to any activity otherwise prohibited by this Article 6 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:

6.2.1. no Celgene Technology, Acceleron Technology or Joint Technology is used in connection with such Third Party activities;

6.2.2. 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 Section 6.2.3 is used in connection with such Third Party activities;

6.2.3. no Know-How relating to any TGF Beta superfamily compounds (including a 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

6.2.4. 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.

6.3 **Acquisitions of Third Parties.** The provisions of this Article 6 do not apply to any activity otherwise prohibited by this Article 6 if Acceleron's involvement or the involvement of any of its Affiliates in such prohibited activity results from Acceleron'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) Acceleron shall, within thirty (30) days after the date of

Acceleron's consummation of such acquisition, notify Celgene of such acquisition and comply with the other provisions of this Section 6.3. Following consummation of such an acquisition, Acceleron shall, at its option, either (i) use good faith efforts to identify a Third Party purchaser to whom Acceleron 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 Acceleron'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 Acceleron'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, Acceleron shall not use any Celgene Technology, Acceleron Technology, or Joint Technology in connection with such Acquired Party Activities. So long as Acceleron 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-011 Agreement.** In the event of termination of the ACE-011 Agreement by Acceleron for cause under Section 11.2.1 of the ACE-011 Agreement, Acceleron's use of any "Licensed Compounds" or "Licensed Products" under the ACE-011 Agreement shall no longer be subject to the provisions of Section 6.1.1 or 6.1.2. For the avoidance of doubt, termination of the ACE-011 Agreement under Section 11.3 or Section 11.4 of the ACE-011 Agreement or expiration of the ACE-011 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-011 Agreement shall continue to be subject to the provisions of Section 6.1.1 or 6.1.2.

Article 7
OPTION PROGRAM

7.1 **Conduct of Option Compound Programs.** Subject to the terms of this Agreement, Acceleron shall be solely responsible for, and shall pay all costs associated with, managing all Development and Manufacturing activities for each Option Compound.

7.2 **Exercise of Option by Celgene**.

7.2.1. Upon Designation as Option Compound. During the Option Term, but subject to Section 7.3, Acceleron may develop, through the filing of an IND, compounds that are to become Option Compounds; provided that Acceleron shall provide Celgene prompt written notice of any compound becoming an Option Compound by virtue of Acceleron filing an IND (which is accepted by the applicable Regulatory Authority) for such

compound for Use in Anemia. Within [* * *] following receipt of such notice, Celgene may provide written notice to Acceleron stating its desire to exercise its option for such Option Compound to be a Licensed Compound hereunder (each such option, an "**Option**"). Effective as of the date of Acceleron's receipt of such notice from Celgene with respect to an Option Compound, Celgene's Option with respect to such Option Compound shall be exercised and the definition of "Licensed Compound" hereunder shall automatically be deemed to include such Option Compound. The notice provided by Acceleron to Celgene that a compound has become an Option Compound shall include (a) a package of all relevant data with respect to such Option Compound, including relevant chemistry, biology, in vitro and in vivo pharmacology, drug metabolism and pharmacokinetics (DMPK) and pilot toxicology; (b) an initial Development Plan/Budget, including a proposed Initial Development Disease; (c) a summary of all Acceleron Technology that covers the applicable Option Compound tested; and (d) such other available information that is reasonably necessary or useful for Celgene to determine whether to exercise its Option. Furthermore, Acceleron will promptly provide Celgene with such additional information and access to records with respect to the applicable Option Compound in Acceleron's possession or available to Acceleron from a Third Party, as Celgene may reasonably request; provided that such request for additional information shall not extend the [* * *] period for Celgene to exercise its Option unless Acceleron fails to provide the requested information in a timely fashion. Upon Celgene's exercise of an Option, the initial Development Plan/Budget proposed by Acceleron (including the proposed Initial Development Diseases), with such changes as are determined by Celgene, in its sole discretion, shall be deemed part of the Development Plan/Budget and deemed approved by the Joint Development Committee.

7.2.2. Following Completion of First Clinical Trial.

(a) If Celgene fails to exercise its Option with respect to an Option Compound pursuant to Section 7.2.1, then during the Option Term, but subject to Section 7.3, Acceleron may further develop such Option Compound through completion of the first Phase 1 Clinical Trial for such Option Compound; provided that Acceleron shall provide Celgene prompt written notice of the final results of such first Clinical Trial for such Option Compound or Option Product. Acceleron's notice shall include the following: (i) the amount of the Option Compound Development Costs incurred by Acceleron up until such date; (ii) an initial Development Plan/Budget, including a proposed Initial Development Disease; and (iii) all relevant data from the Clinical Trial, including all summary data tables, statistical analyses, and statistical reports related to the endpoints derived from such Clinical Trial, the underlying information used to create such summaries, case report forms (as available), and all other preclinical data generated; (iv) manufacturing data (including CMC); (v) any related correspondence (excluding non-substantive correspondence) or information received from or sent to any Regulatory Authority; (vi) a report of analysis of the top line data from a locked data base using validated programs for all of the primary and secondary endpoints (and exploratory, if applicable) for the compound tested in such Clinical Trial, as specified in applicable protocol and statistical analysis plan; (vii) a summary of all

Acceleron Technology that covers the Option Compound tested in such Clinical Trial; and (viii) such other available information that is reasonably necessary or useful for Celgene to determine whether to exercise its Option. Furthermore, Acceleron will promptly provide Celgene with such additional information and access to records with respect to the applicable Option Compound in Acceleron's possession or available to Acceleron from a Third Party, as Celgene may reasonably request; provided that such request for additional information shall not extend the [* * *] period for Celgene to exercise its Option pursuant to Section 7.2.2(b) unless Acceleron fails to provide the requested information in a timely fashion.

(b) Within [* * *] following receipt of Acceleron's notice pursuant to Section 7.2.2(a), Celgene may provide written notice to Acceleron stating its desire to exercise its Option for such Option Compound. In addition, at any time until the expiration of such [* * *] period, regardless of whether Acceleron has provided the notice pursuant to Section 7.2.2(a), Celgene may provide written notice to Acceleron stating its desire to exercise its Option with respect to any compound that has become an Option Compound pursuant to Section 7.2.1; provided that such right shall only apply with respect to Option Compounds that Acceleron has not already (x) granted any Third Party any rights or (y) filed an IND (which is accepted by the applicable Regulatory Authority) in a field outside of Use in Anemia, in each case, as permitted by Section 7.2.3.

(c) If Celgene elects to exercise its Option under this Section 7.2.2 with respect to an Option Compound, it shall pay Acceleron [* * *] of the Option Compound Development Costs incurred by Acceleron with respect to such Option Compound through the date of Acceleron's receipt of Celgene's written notice of its election to exercise of such Option, which payment Celgene shall make within [* * *] days of providing Acceleron such written notice. Effective as of the date of Acceleron's receipt of such payment from Celgene with respect to an Option Compound, Celgene's Option with respect to such Option Compound shall be exercised and the definition of "Licensed Compound" hereunder shall automatically be deemed to include such Option Compound. Upon Celgene's exercise of an Option, the initial Development Plan/Budget proposed by Acceleron (including the proposed Initial Development Diseases), with such changes as are determined by Celgene, in its sole discretion, shall be deemed part of the Development Plan/Budget and deemed approved by the Joint Development Committee.

7.2.3. Termination of Option. In the event Celgene does not exercise its Option in accordance with Section 7.2.1 or 7.2.2 with respect to an Option Compound, then, subject to Section 7.2.4, Celgene shall have no further rights to such Option Compound, and Acceleron shall be subject to the restrictions of Article 6 with respect to such Option Compound but Acceleron shall otherwise have the right to further exploit (including licensing to Third Parties subject to Section 7.3) such Option Compound other than for Use in Anemia.

7.2.4. Option Term Extension.

(a) If a Change of Control of Acceleron occurs, then at that time Celgene shall have an Option on the following:

(i) any Option Compounds not selected by Celgene pursuant to Section 7.2.1 or 7.2.2, but only if Acceleron has not already (x) granted any Third Party any rights to such compound or (y) filed an IND (which is accepted by the applicable Regulatory Authority) on such compound in a field outside of Use in Anemia, in each case, as permitted by Section 7.2.3, and

(ii) any pre-IND compounds under development by Acceleron for which Acceleron intends to file an IND for Use in Anemia with respect to which pre-IND compounds Acceleron has completed toxicology studies and Acceleron has not granted any Third Party any rights ("**Pre-IND Anemia Compounds**").

(b) At such time as Celgene's option under this Section 7.2.4 would apply, Acceleron shall deliver to Celgene written notice setting forth (i) a list of all Option Compounds described in Section 7.2.4(a)(i) and (ii) a list of all Pre-IND Anemia Compounds, together with relevant available data with respect to such Option Compounds and Pre-IND Anemia Compounds (which shall include the information described in Section 7.2.1 or 7.2.2 to the extent available). Within [* * *] days following receipt of such notice, Celgene may provide written notice to Acceleron stating its desire to exercise its option for any such Option Compound or any such Pre-IND Anemia Compound to be a Licensed Compound hereunder. Effective as of the date of Acceleron's receipt of such notice from Celgene with respect to any such Option Compound or any such Pre-IND Anemia Compound, Celgene's Option with respect to such compound shall be exercised and the definition of "Licensed Compound" hereunder shall automatically be deemed to include such compound. Furthermore, Acceleron will promptly provide Celgene with such additional information and access to records with respect to the applicable Option Compound or Pre-IND Anemia Compound in Acceleron's possession or available to Acceleron from a Third Party, as Celgene may reasonably request; provided that such request for additional information shall not extend the [* * *] period for Celgene to exercise its Option unless Acceleron fails to provide the requested information in a timely fashion. Upon Celgene's exercise of an Option, the initial Development Plan/Budget proposed by Acceleron, if any (including the proposed Initial Development Diseases), with such changes as are determined by Celgene, in its sole discretion, shall be deemed part of the Development Plan/Budget and deemed approved by the Joint Development Committee; provided that Acceleron shall not be required as part of its notice under this Section 7.2.4 to propose a Development Plan/Budget, in which event Celgene shall prepare a draft, which shall be deemed approved by the Joint Development Committee.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

7.3 **Licensing Restrictions; Option Compounds and Products.** During the Option Term and subject to this Article 7, (a) neither Acceleron nor any of its Affiliates shall grant any rights to an Option Compound or Option Product in the Territory to a Third Party prior to the termination of the Option for such Option Compound or Option Product in accordance with Section 7.2.3; and (b) following the termination of the Option for an Option Compound or Option Product, neither Acceleron nor any of its Affiliates shall grant any rights to an Option Compound or Option Product in the Territory to a Third Party except subject to the prohibitions set forth in Article 6.

7.4 **Updates; Reports.** For so long as Celgene's option under this Article 7 remains in place, Acceleron shall provide Celgene with regular updates no less than once a [* * *] on the results of all Option Compound development programs, including written notice within [* * *] days of the dosing of the first patient in the first Clinical Trial of an Option Compound or Option Product. 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 **Third Party Patent Rights.**

8.1.1. Celgene acknowledges that the Acceleron Patent Rights listed on Schedule 8.1.1, which Schedule 8.1.1 (the "**Third Party Patent Rights**") have been licensed by Acceleron from the Third Party Licensors pursuant to the Third Party Licenses. Acceleron, with Celgene's consent, may amend Schedule 8.1.1 from time to time update the Third Party Patent Rights under the Third Party Licenses.

8.1.2. Acceleron agrees to provide to Celgene all information and copies of documents received from the Third Party Licensors or their respective patent counsel relating to the Third Party 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 Third Party Patent Rights, then such Third Party Patent Rights shall be treated in the same manner as other Acceleron Patent Rights under this Article 8, and Acceleron shall exercise all such rights with respect to the Third Party Patent Rights pursuant to the instructions of Celgene, if Celgene is given the first right to act under this Article 8.

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 the Licensed Product Patents (and, for clarity, will be the "Prosecuting Party" with respect to the Acceleron Patent Rights and the Licensed Product Patents), 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 30 days 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 in Section 8.2.1(a)(i), 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 thirty (30) days 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, after the Effective Date, 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) Common Interest. 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.

(d) Licensed Product Patent. If any Acceleron Patent Right (other than a Licensed Product Patents) has any claim, or the specification of such Patent Right supports a claim(s), directed only to Licensed Compounds or Licensed Products, then, upon Celgene's request, the Parties will co-operate to file divisional or continuation applications, as applicable, to separate such claims from the rest of the Acceleron Patent Right or add claims supported by such specifications and separate such added claims, and such divisional or continuation shall thereafter be deemed a "Licensed Product Patent."

(e) Shire Agreement. The Parties acknowledge and agree that (i) pursuant to the Shire Agreement, Shire has been granted certain rights to Prosecute Patent Rights that may be Acceleron Patent Rights hereunder if Acceleron elects not to Prosecute such Patent Rights, and Celgene's right to Prosecute such Patent Rights hereunder are subject to Shire's prior rights; and (ii) to the extent that Shire is Prosecuting such Patent Rights, Acceleron shall keep Celgene informed in accordance with this Section 8.2.1 and shall use commercially reasonable efforts to cause Shire to take the actions specified by this Section 8.2.1, if applicable to such Patent Right, in a manner consistent with the Shire Agreement; provided that Acceleron will not be in breach of its obligations under this Section 8.2.1 if, after using such commercially reasonable efforts, it is unable to comply with such obligations because of actions taken or not taken by Shire.

(f) Additional Claims. For purposes of Prosecution of the Acceleron Patent Rights and Licensed Product Patents, the Prosecuting Party shall use reasonable efforts to seek to obtain claims directed to (i) [* * *] and (ii) [* * *]. If Shire is responsible for Prosecuting Acceleron Patent Rights that would be subject to this Section 8.2.1(f), Acceleron shall use Commercially Reasonable Efforts to cause Shire to seek such claims.

8.2.2. Celgene Patent Rights. 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.

8.2.3. Cooperation. 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 Section 8.2.4, any Patent Procurement Costs owed by Acceleron to any 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. Notification. 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.

(a) 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) to the extent permitted by 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 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) Acceleron Collaboration IP; Joint Technology. 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) Celgene Technology. 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.

(d) Shire Agreement. The Parties acknowledge and agree that (i) pursuant to the Shire Agreement, Shire has been granted the right to take measures it deems appropriate to stop infringing activities in respect to Patent Rights and Know-How (which may be Acceleron Technology hereunder) in respect to "Licensed Compounds" and "Licensed Product" in the "Field" (each as defined in the Shire Agreement) in all countries of the world other than those of North America if Acceleron elects not to take any action, and Celgene's right to enforce such Patent Rights and Know-How are subject to Shire's prior rights; and (ii) to the extent that Shire is enforcing such Patent Rights or Know-How, Acceleron shall keep Celgene informed in accordance with this Section 8.3 and shall use commercially reasonable efforts to cause Shire to take the actions specified by this Section 8.3, if applicable to such Patent Right or Know-How, in a manner consistent with the Shire Agreement; provided that Acceleron will not be in breach of its obligations under this Section 8.3 if, after using such commercially reasonable efforts, it is unable to comply with such obligations because of actions taken or not taken by Shire.

8.3.3. Procedures; Expenses and Recoveries. The Party having the right to initiate any infringement suit under Section 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 Section 8.3.2(a) or 8.3.2(b), 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 [* * *].

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. Right to Defend. 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. Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTION 11.7, 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 Sections 8.3 and 8.4 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 the fusion protein ACE-536.

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 Information.**

8.8.1. Cooperation. Upon Celgene's request any time after completion of the first Phase 2 Clinical Trial for any Licensed Product, Acceleron shall, at Celgene's expense, use reasonable efforts to assist and cooperate with Celgene in establishing a strategy for responding to requests for information from Regulatory Authorities and Third Party requestors and preparing submissions responsive to any Biosimilar Notices received by Celgene; provided that Celgene shall make the final decisions with respect to such strategy and any such responses.

8.8.2. Biosimilar Notices. Celgene shall comply with the applicable provisions of 42 U.S.C. § 262(1) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future regarding biologic products in the United States, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction, in each case, with respect to any Biosimilar Notice received by Celgene from any Third Party regarding any Licensed Product that is being Commercialized in the applicable jurisdiction, and the exchange of information between any Third Party and Celgene pursuant to such requirements; provided that, [* * *]; provided further that [* * *]. Celgene shall give written notice to Acceleron of receipt of a Biosimilar Notice received by Celgene with respect to a Licensed Product, and Celgene shall consult with Acceleron with respect to the selection of the Patent Rights to be submitted pursuant to 42 U.S.C. § 262(1) (or any similar law in any country of the Territory outside the United States); provided that [* * *]. Acceleron agrees to be bound by the confidentiality provisions of 42 U.S.C. § 262(1)(1)(B)(iii). In order to establish standing in connection with any action brought by Celgene under this Section 8.8.2, Acceleron, upon Celgene's request, shall reasonably cooperate with Celgene in any such action at Celgene's expense, including timely commencing or joining in any action brought by Celgene under this Section 8.8.2 solely to the extent Acceleron Patent Rights are involved in any such action. Notwithstanding anything to the contrary in this Section 8.8, (a) if Acceleron Patent Rights or Joint Patent Rights are involved in any action brought by Celgene under this Section 8.8.2, [* * *], and (b) [* * *].

8.9 **Patent Term Extensions**. The Parties shall use reasonable efforts to obtain all available supplementary protection certificates, patent term restorations, and other extensions (collectively, "**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 Extensions wherever applicable to Acceleron Patent Rights or Joint Patent Rights. The holder of the applicable NDA may determine what Extensions of any such Patent Rights shall be made; provided that, if in any country such holder 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 such an Extension, 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, as determined by the holder of the applicable NDA, shall be made by the Party to whom responsibility for Prosecution of the Acceleron Patent Rights or Joint Patent Rights are assigned, and the owner of record of the applicable Patent Right shall assist with such filings; provided that, in the event that the Party to whom such responsibility is assigned elects not to file for an Extension, 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 in the Patent Rights' owner's name, and (c) provide all necessary assistance in connection therewith. The Parties acknowledge and agree that (i) pursuant to the Shire Agreement, Shire and Acceleron will consult in selecting Patent Rights to extend the patent term with respect to "Licensed Products" under the Shire Agreement, and Shire shall make the decision in all countries of the world other than those of North America with respect to such "Licensed Products" under the Shire Agreement, and the filings for Extensions with respect thereto will be made by the party who is responsible for Prosecuting Patent Rights under the Shire Agreement, and, as such, Celgene's rights under this Section 8.9 are subject to Shire's prior rights; and (ii) Acceleron shall keep Celgene informed of all elections with respect to Extensions made pursuant to the Shire Agreement that affect Acceleron Patent Rights, and, to the extent that Shire is making any such elections, Acceleron shall use commercially reasonable efforts to cause Shire to take the actions specified by this Section 8.9 in a manner consistent with the Shire Agreement; provided that Acceleron will not be in breach of its obligations under this Section 8.9 if, after using such commercially reasonable efforts, it is unable to comply with such obligations because of actions taken or not taken by Shire.

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 Article 9. Each Party shall be responsible for a breach of this Article 9 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 Article 9 shall expire [* * *] following termination or expiration of this Agreement.

9.1.2. Authorized Disclosure. Notwithstanding the provisions of Sections 9.1.1, 9.2, or 9.3, 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 Article 8; provided 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); provided 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 Section 9.1.2, 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.

9.1.4. ACE-011 Agreement. 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-011 Agreement and *vice versa.* Therefore, the Parties agree that information can be deemed Confidential Information under this Agreement and "Confidential Information" under the ACE-011 Agreement and that such

information will be subject to the confidentiality and non-use obligations of both agreements.

9.1.5. Joint Technology. The Parties agree that, in order to effectuate the provisions of Section 4.4.2, subject to any exclusive licenses granted hereunder, (a) the non-use provisions of this Article 9 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.

9.2 **Publication Review.** Notwithstanding anything to the contrary in this Agreement, except as required by Applicable Law, from and after the Effective Date, the Developing Party shall have the sole right to publish or present the results of any work relating to the Development of Licensed Products or Licensed Compounds in the Field for which such Developing Party is responsible under this Agreement (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 and to ensure intellectual property protection. 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 [* * *] 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 [* * *] to provide feedback. The Party that is not the Publishing Party (i) 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; (ii) may require that the Publishing Party delay publication for a sufficiently long period not to exceed [* * *] in order to permit the timely preparation and filing of a patent application; and (iii) may request changes the non-Publishing Party reasonably believes are necessary to preserve any Patent Rights or Know-How belonging (whether through ownership or license, including under this Agreement) in whole or in part to the non-publishing Party or are necessary to avoid negatively impacting the Development or Commercialization of a Licensed Compound or Licensed Product, which changes, in either case, the Publishing Party will consider in good faith. Notwithstanding anything to the contrary in this Agreement, for the purpose of publication in accordance with this Section 9.2, Know-How shall not include data generated in the course of Clinical Trials conducted by the Publishing Party (as Developing Party) hereunder.

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 Section 9.1.2. 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 xpressly 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 3 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 2 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 3 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
TERM AND TERMINATION

10.1 **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 10, 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) the end of the Option Term. For the avoidance of doubt, Section 10.1(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.

10.2 **Termination for Cause.**

10.2.1. Cause for Termination. 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.

10.2.2. Effect of Termination for Cause.

(a) Termination by Acceleron. Without limiting any other legal or equitable remedies that Acceleron may have, if Acceleron terminates this Agreement in accordance with Section 10.2.1, then, except for the licenses granted in Section 10.5, all licenses granted under this Agreement shall terminate.

(b) Termination by Celgene. Without limiting any other legal or equitable remedies that Celgene may have, if Celgene terminates this Agreement in accordance with Section 10.2.1, then the license granted to Acceleron pursuant to Section 4.2 shall terminate, the licenses granted to Celgene under Section 4.1 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 Section 2.1.3 (Additional Development Diseases) and Article 6 (Exclusivity) shall survive such termination for as long as Celgene is paying or has an obligation to pay royalties (including a future obligation to pay royalties with respect to a Licensed Product being Developed hereunder that has not yet been Commercialized) pursuant hereto; and (iv) Acceleron shall continue to be solely responsible for all royalty, milestone, and other payments owed to any 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); provided that, if Acceleron is the Breaching Party and Celgene terminates this Agreement in accordance with Section 10.2.1(a) for a breach by Acceleron of its material obligations under Article 6 (Exclusivity) or if Acceleron breaches such Article 6 (Exclusivity) following termination during the period such obligations survive as provided in this Section 10.2.2(b), 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 other Third Parties pursuant to Section 5.6.3(d) with respect to activities of Celgene in exercising such licenses.

10.3 **Termination for Convenience.** At any time after Completion of the Acceleron Phase 2 Clinical Trials, 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 [* * *] advance written notice to Acceleron; provided that, if (a) an Acceleron Phase 2 Clinical Trial is put on Clinical Hold, (b) Acceleron has not initiated any Acceleron Phase 2 Clinical Trial *(i.e.,* dosing of first patient) by no later than the third anniversary of the Effective Date, or (c) Acceleron has not Completed the Acceleron Phase 2 Clinical Trials by no later than the seventh anniversary of the Effective Date, then Celgene may terminate this Agreement even if the Acceleron Phase 2 Clinical Trials have not been Completed.

10.4 **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 Section 3.3 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 [* * *] advance written notice to Acceleron.

10.5 **Other Effects of Termination.** In the event that Acceleron terminates this Agreement for cause under Section 10.2.1 or Celgene terminates this Agreement for convenience under Section 10.3 or for failure to meet end points under Section 10.4:

10.5.1. License and Assignment. 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 Section 4.3), 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 Article 7) 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 Section 10.3 or for failure to meet clinical endpoints under Section 10.4, and (ii) royalty-bearing in the event that Acceleron terminates this Agreement for any other cause under Section 10.2.1, 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 Sections 5.6.3(c) or 5.6.3(d), (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 *mutatis mutandis.*

10.5.2. Transfer of Materials. In the event Acceleron exercises its rights pursuant to Section 10.5.1, 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.

10.5.3. Confidential Information. Notwithstanding Section 9.1.1, 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 Section 10.5.1 remain Confidential Information, Acceleron's obligations of confidentiality pursuant to Article 9 shall survive and continue in full force and effect.

10.5.4. Continuity of Supply. Except in the event of a termination of this Agreement pursuant to Section 10.4, 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 [* * *] period 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 10.5.1.

10.6 **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 Article 5 of this Agreement.

10.7 **Transfer of Records.** Upon expiration of this Agreement or in the event that Celgene terminates this Agreement for cause under Section 10.2.1, Acceleron will continue to maintain all records described in Section 2.2 or transfer them to Celgene, as requested by Celgene.

10.8 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Acceleron or Celgene, including Article 4, 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.

10.9 **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 Article 6 (to the extent provided in Section 10.2.2(b)), Article 9, Article 10, Article 11, Article 12 and Sections 4.3.3, 4.4, 4.5.3, 8.4.4, 11.5, 11.6, 11.7, as well as Sections 2.2, 2.3.5, 2.4.7, 2.9.1, 8.1, 8.2, 8.3, and 8.6 (but, with respect to such sections of Article 2 and Article 8, only to the extent that Celgene's exclusive license survives pursuant to Section 10.2.2(b)) shall survive any expiration or termination of this Agreement. Except as set forth in this Article 10, 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 11
REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

11.1 **Mutual Representations and Warranties.** Each Party represents and warrants to the other Party that as of the Effective Date of this Agreement:

11.1.1. 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 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.

11.1.2. 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.

11.1.3. 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.

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

11.2.1. 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 are set forth on Schedule 1.5 and 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 Technology in any manner that would adversely affect Celgene's exercise of its rights hereunder.

11.2.2. No Patent Rights or other intellectual property rights licensed to Acceleron under either (a) that certain Exclusive License Agreement dated August 10, 2010 between Acceleron and the Salk Institute for Biological Studies or (b) that certain Exclusive License Agreement dated August 11, 2010 between Acceleron and the Salk Institute for Biological Studies relate to or are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field. Celgene shall not have any obligations under (including any financial obligations), or be subject to any restrictions set forth in, either such agreement with Salk Institute for Biological Studies.

11.2.3. To the best knowledge of Acceleron and its Affiliates, there is no actual or threatened infringement of the Acceleron 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.

11.2.4. 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.

11.2.5. The Third Party Licenses, as provided to Celgene, are each in full force and effect and none has been modified or amended.

11.2.6. Neither Acceleron nor, to the best knowledge of Acceleron, any Third Party Licensor 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, any Third Party License.

11.2.7. There are no Third Party Patent Rights. There are no Patent Rights or Know-How Controlled by Acceleron through a license from a Third Party that are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field, including no Patent Rights or Know-How licensed to Acceleron pursuant to the agreements set forth on Schedule 11.2.13(a) that are necessary or useful to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field.

11.2.8. Acceleron has not waived or allowed to lapse any of its rights under any Third Party License with respect to Licensed Compounds or Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.

11.2.9. 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.

11.2.10. The Acceleron 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.

11.2.11. To the best knowledge of Acceleron or its Affiliates, each of the issued Acceleron Patent Rights is valid and enforceable.

11.2.12. For purposes of exercising its rights or performing its obligations hereunder in Developing, Manufacturing and Commercializing Licensed Compounds or Licensed Product in the Field, Celgene does not need access or a license to, 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.

11.2.13. Acceleron has not previously (a) except as set forth in Schedule 11.2.13(a), engaged any Third Party in connection with performance of any of its obligations hereunder or entered into any license with any Third Party, in either case, with respect to ACE-536 or (b), entered into an agreement with a Third Party to obtain a

license under Third Party Intellectual Property that covers the offering for sale, selling, making, having made, using or importing ACE-536 in the Field in the Territory (including rights of a pending patent application that are reasonably expected to issue).

11.2.14. Acceleron has not granted 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, other than to Shire pursuant to the Shire Agreement.

11.2.15. Acceleron has provided to Celgene a redacted version of the Shire Agreement. The terms and conditions of the Shire Agreement do not conflict with the rights granted to Celgene by Acceleron hereunder. None of the Acceleron Technology licensed to Celgene from Acceleron hereunder is sublicensed from Shire pursuant to the Shire Agreement, and, to the best knowledge of Acceleron, no Patent Rights or Know-How of Shire is necessary to Develop, Manufacture or Commercialize a Licensed Compound or a Licensed Product in the Field. None of the redacted terms and provisions of the Shire Agreement materially affect or materially impact the rights or obligations of Celgene under this Agreement or the ACE-011 Agreement or Acceleron's ability to perform under this Agreement or the ACE-011 Agreement. None of Acceleron's obligations hereunder or the rights granted to Celgene hereunder shall violate any obligations of Acceleron or rights of Shire under the Shire Agreement.

11.2.16. The sequence of the protein known by Acceleron as ACE-536 shown in Schedule 1.9 is complete and accurately reflects the corresponding protein product. Such sequence is identical to the sequence for ACE-536 submitted by Acceleron to the FDA for purposes of obtaining Regulatory Approval of the corresponding ACE-536 protein product and identical to the sequence of the "Excluded Compound" as defined in the Shire Agreement.

11.3 **Option Compound Representations and Warranties.** Immediately prior to an Option Compound becoming a "Licensed Compound" pursuant to Article 7, Acceleron shall represent and warrant to Celgene the matters set forth in Section 11.2 with respect to such Option Compound and related Option Patent Rights or shall notify Celgene of which representations and warranties, if any, are untrue. In addition, to the extent that any Option Patent Rights include Third Party Patent Rights, Acceleron shall represent and warrant to Celgene, as of the date an Option Compound becomes a Licensed Compound, the following or shall notify Celgene of which representations and warranties, if any, are untrue:

11.3.1. to the best knowledge of Acceleron, the Third Party Patent Rights were not and are not subject to any restrictions or limitations except as set forth in the Third Party Licenses, true and correct copies of which have been provided to Celgene; and

11.3.2. To the best knowledge of Acceleron or its Affiliates, the Third Party 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.

11.4 **Celgene Covenants, Representations and Warranties.**

11.4.1. Covenants. In addition to the covenants made by Celgene to Acceleron elsewhere in this Agreement, Celgene hereby covenants to Acceleron that, during the Agreement Term:

(a) (i) If Acceleron believes that any of Celgene or its Affiliates or Sublicensees is engaging or intends to engage in an activity to develop, manufacture or commercialize ACE-536 in a manner that causes or will cause a Material Adverse Impact, then Acceleron shall provide Celgene with written notice. Celgene agrees to negotiate in good faith with Acceleron with respect to modifying the applicable activity to cease causing a Material Adverse Impact; provided that, if the Parties are unable to agree on how to modify the activity or whether the activity causes or will cause a Material Adverse Impact, then, except as provided in clause (ii) below, Celgene, its Affiliates or Sublicensees shall not be prohibited from continuing the activity.

(ii) If (A) (1) pursuant to the dispute resolution provisions in the Shire Agreement, it is determined that a Material Adverse Impact exists (other than a resolution of a dispute that results merely from an agreement between Acceleron and Shire) or (2) a final arbitration award has specified or a court has entered an order or judgment confirming that a Material Adverse Impact exists, in either case, which Material Adverse Impact affects Shire (not just Acceleron) and in which dispute resolution procedure or arbitration procedure, as applicable, Acceleron has advocated Celgene's position that there is no Material Adverse Impact, and (B) such Material Adverse Impact is due to Celgene's, its Affiliates' or its Sublicensees' activities Developing, Manufacturing or Commercializing ACE-536, Celgene shall cease the applicable activity causing the Material Adverse Impact immediately upon receipt of written notice from Acceleron. Celgene shall not be responsible for any damages resulting from the Material Adverse Impact, whether to Acceleron, Shire, or otherwise, except to the extent such damages result from the failure by Celgene to cease the applicable activity after Celgene's receipt of notice pursuant to this Section 11.4.1(a)(ii).

(b) Celgene shall not, prior to [* * *], (a) with respect to any Option Compound that is a [* * *], (i) conduct any Clinical Trial whose primary endpoint is the [* * *]; (ii) seek or obtain Regulatory Approval for such Option Compound for the [* * *]; (iii) conduct any Clinical Trial for the [* * *]; or (iv) market or promote such Option Compound for the [* * *]; or (b) license to any Third Party any Acceleron Patent Rights in any such Option Compound that is a [* * *] unless such license agreement requires the licensee to comply with this Section 11.4.1(b) until [* * *].

(c) If Acceleron breaches the representation and warranty in Section 11.2.16, without limiting any other remedy Celgene may have, (i) Acceleron will use

reasonable efforts to amend the Shire Agreement to provide that the "Excluded Compound" as defined in the Shire Agreement has a sequence identical to the sequence for the corresponding protein product used by Acceleron in connection with its Clinical Trials under this Agreement for obtaining Regulatory Approval; and (ii) upon such amendment, Acceleron agrees that it will execute an amendment to this Agreement to cause the definition of "ACE-536" hereunder to be identical to such sequence.

11.4.2. Representation and Warranty. Celgene represents and warrants to Acceleron that 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.

11.5 **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.

11.6 **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 SECTION 11.6 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 [* * *].

11.7 **Indemnification and Insurance.**

11.7.1. Indemnification by Celgene. 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.

11.7.2. Indemnification by Acceleron. 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.

11.7.3. Indemnification Procedure. In the event of any such claim against any Celgene Indemnitee or Acceleron Indemnitee (individually, an **"Indemnitee**"), 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 Section 11.7.1 or 11.7.2 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; provided 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 Article 11 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.

11.7.4. Joint Defendants. 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 Section 11.7.1 or 11.7.2 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 Section 11.7.1 or 11.7.2 above, then the indemnification provisions of either Section 11.7.1 or 11.7.2 above, whichever is applicable, and the indemnification procedures of Section 11.7.3 shall become applicable and govern further proceedings in the suit, and the Party responsible for such claim shall reimburse the other Party for all costs that would have been the indemnifying Party's responsibility if it had been apparent from the beginning that the indemnification provisions applied.

11.7.5. Insurance. 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 Section 11.7.1 or 11.7.2 above, as applicable) in amounts not less than [* * *] per incident and [* * *] annual aggregate; provided 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 Section 11.7.5 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligation under Section 11.7.1 or 11.7.2 above, as applicable.

Article 12
MISCELLANEOUS PROVISIONS

12.1 **Dispute Resolution; Governing Law.**

12.1.1. Disputes. 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 Section 12.1.1 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.

12.1.2. Jurisdiction. 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.

12.1.3. Governing Law. 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.

12.2 **Assignment.** Except as provided in this Section 12.2, 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.

12.3 **Amendments.** This Agreement and the Schedules referred to in this Agreement, together with the ACE-011 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.

12.4 **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.
128 Sidney Street
Cambridge, MA 02139
Attn: President
Telephone: (617) 649-9200
Fax: (617) 576-2224

with a copy to: Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199
Attn: Marc A. Rubenstein
Telephone: (617) 951-7000
Fax: (617) 235-0706

If to Celgene: [* * *

with a copy to:

]
Fax: (908) 673-2771

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

12.5 **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; provided 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; provided further 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.

12.6 **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.

12.7 **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.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

12.8 **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.

12.9 **No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

12.10 **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.

12.11 **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.

12.12 **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.

12.13 **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.

12.14 **Execution in Counterparts.** This Agreement may be executed in two or more 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. Facsimile or PDF execution and delivery of this Agreement by any Party shall constitute a legal, valid and binding execution and delivery of this Agreement by such Party.

[Signature page follows]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[* * *]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

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: /s/ John Knopf
Name: John Knopf
Title: Chief Executive Officer

CELGENE CORPORATION

By: /s/ Robert J. Hugin
Name: Robert J. Hugin
Title: Chairman and Chief Executive Officer

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EXHIBIT A

TERMS OF CLINICAL SUPPLY

Firm Orders:	[* * *]
Quantities of Clinical Supplies:	[* * *]
Delivery of Clinical Supplies:	[* * *]
Adjustments:	[* * *]

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SCHEDULE 1.5
ACCELERON PATENT RIGHTS

Table 1: Patents and Applications Owned by Acceleron Pharma, Inc.

Attorney Docket Number	Application Number	Patent/Publ. Number	Status	Title	Filing Date	Issue/Publ. Date
[●]	[●]	[●]	[●]	[●]	[●]	[●]

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SCHEDULE 1.9
ACE-536

[* * *]

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SCHEDULE 1.104
THIRD PARTY LICENSES

[* * *]

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SCHEDULE 3.7
DESIGNATED THIRD PARTY ACQUIRORS

[* * *]

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SCHEDULE 4.4.6
OUTSIDE COUNSEL FOR INVENTORSHIP/PATENT DISPUTES

[* * *]

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SCHEDULE 8.1.1
THIRD PARTY PATENT RIGHTS

None.

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SCHEDULE 9.3
PRESS RELEASE

Acceleron Pharma Announces Global Collaboration with
Celgene Corporation on ACE-536 Program

Expands Upon Existing Sotatercept (ACE-011) Partnership by Entering a New Agreement to Form Broad Anemia Collaboration

SUMMIT, NJ and CAMBRIDGE, Mass. C August 3, 2011 C Acceleron Pharma, Inc., a biopharmaceutical company developing protein therapeutics for cancer and orphan diseases, and Celgene Corporation (NASDAQ: CELG) today announced that the companies have entered into a joint development and commercialization agreement for ACE-536 for the treatment of anemia. The companies already have a collaboration around sotatercept (ACE-011) entered in 2008. Under the new agreement, the companies will collaborate to develop both products and potentially others for treating anemia across a wide range of indications.

Celgene and Acceleron will jointly develop, manufacture and commercialize ACE-536, a novel protein therapeutic that inhibits members of the TGF-beta superfamily involved in erythropoiesis, for the
treatment of anemia. Additionally, Celgene will have an option to future Acceleron programs developed
for anemia. Celgene will make an upfront payment to Acceleron of $25 million.

"Acceleron has uncovered an exciting new approach to treating disorders of erythropoiesis, and we are pleased to broaden our successful partnership with Celgene," said John Knopf, Ph.D., Chief Executive Officer of Acceleron. "Acceleron and Celgene can now combine our strengths to develop molecules to treat a broad array of under-served diseases and conditions in which patients suffer from anemia. To that end, we look forward to initiating the Phase 1 clinical trial of ACE-536 within the next few months. ACE- 536 is our fourth internally discovered and developed drug to enter the clinic."

"Celgene and Acceleron have a strong partnership that continues to advance innovative therapies in areas of great unmet medical need," said Tom Daniel, Ph.D., President, Research, Celgene. "The work we will embark on with ACE-536 is a natural extension of our strong presence in hematology. We look forward to exploring the potential of ACE-536 for patients with anemia worldwide."

Under the terms of the agreement, Acceleron will be responsible for conducting the Phase 1 and initial Phase 2 clinical trials and Celgene will conduct the subsequent Phase 2 and Phase 3 clinical studies. Acceleron will manufacture ACE-536 for the Phase 1 and Phase 2 clinical trials and Celgene will have responsibility for the manufacture of Phase 3 and commercial supplies. Acceleron will pay a share of the development expenses through the end of 2012 and Celgene will be responsible for development costs thereafter. Acceleron is eligible to receive development, regulatory and commercial milestones of up to $217 million for the ACE-536 program. The companies will co-promote the products in North America. Acceleron will receive tiered double-digit royalties on worldwide net sales.

About ACE-536

ACE-536 is a ligand trap that inhibits members of the TGF-beta superfamily involved in late stages of erythropoiesis. ACE-536 and sotatercept are biochemically distinct molecules and may have unique pharmacological attributes that enable their preferential use in particular anemia indications. In preclinical studies, ACE-536 promotes red blood cell (RBC) formation in the absence of erythropoietin (EPO) signaling, has distinct effects from EPO on RBC differentiation, and acts on a different population of progenitor blood cells than EPO during RBC development.

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About ACE-011 / sotatercept

Sotatercept, a soluble receptor fusion protein comprised of extracellular domain of the human activin receptor type IIA (ActRIIA) fused to human immunoglobulin, is a biologic therapeutic. Blocking signaling through ActRIIA may be a way to increase red blood cell production, promote bone formation, and inhibit tumor growth and metastasis. Sotatercept is the first in a novel class of anemia therapies. In Phase 1 clinical studies in healthy volunteers, sotatercept was generally well tolerated, and increased levels of hemoglobin and hematocrit, biomarkers of bone formation, and bone mineral density. The most common clinically significant adverse events observed included increased hemoglobin and increased hematocrit, which were pharmacologic effects of the drug, and also headache, all of which were manageable and reversible. Sotatercept is currently being studied in Phase 2 clinical trials in patients with chemotherapy- induced anemia and in patients with end-stage renal disease on hemodialysis. For more information on ongoing and completed clinical trials of sotatercept, visit clinicaltrials.gov and query "sotatercept." Sotatercept is being jointly developed by Acceleron and Celgene Corporation.

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.

About Acceleron

Acceleron is a privately-held biopharmaceutical company committed to discover, develop, manufacture and commercialize novel protein therapeutics for orphan diseases and cancer. Acceleron's scientific approach takes advantage of its unique insight to discover first-in-class therapies based on the TGF- protein superfamily. Acceleron utilizes proven biotherapeutic technologies and capitalizes on the company's internal GMP manufacturing capability to advance its therapeutic programs rapidly and efficiently. The investors in Acceleron include Advanced Technology Ventures, Alkermes, Bessemer Ventures, Celgene, Flagship Ventures, MPM BioEquities, OrbiMed Advisors, Polaris Ventures, QVT Financial, Sutter Hill Ventures and Venrock. For further information on Acceleron, please visit www.acceleronpharma.com.

CONTACT:

Acceleron Pharma:
Steven Ertel, 617-649-9234
Senior Vice President, Corporate Development

Celgene Corporation:
Brian Gill, 908-673-9530
VP, Corporate Communications

Maureen L. Suda (Media)
Suda Communications LLC, 585-387-9248

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SCHEDULE 11.2.13

ACE-536 CONTRACTS

[†]

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER, ACCELERON PHARMA INC.

I, Habib J. Dable, 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 5, 2021	/s/ Habib J. Dable
Date	Habib J. Dable Chief Executive Officer and President (Principal Executive Officer)

Exhibit 31.2

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 5, 2021	/s/ Kevin F. McLaughlin
Date	Kevin F. McLaughlin Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Acceleron Pharma Inc. (the "Company") for the period ended June 30, 2021 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 5, 2021

By: /s/ Habib J. Dable

Habib J. Dable
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2021

By: /s/ Kevin F. McLaughlin

Kevin F. McLaughlin
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)